80-015

United States
Environmental Protection
Agency

Office of Pesticides and
Toxic Substances
Washington, D.C. 20460

EPA-560/13-80-015
May 1980

Toxic Substances

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Toxics Integration Information Series

EPA-560/13-80-015

# FEDERAL ACTIVITIES
# IN
# TOXIC SUBSTANCES

Edited by
Judith Collé

With the Assistance of
Elaine Schosman
Kathryn Slike

Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
May 1980

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# FOREWORD

In 1976, one of the most comprehensive pieces of Federal environmental legislation, the Toxic Substances Control Act (TSCA) was enacted. TSCA was designed to address both the overlaps and the gaps in existing health and environmental legislation. The Act provides broad authority to the Environmental Protection Agency (EPA) to regulate the thousands of chemicals in commerce. TSCA directs EPA to take appropriate regulatory action if any of these chemicals are found to present an unreasonable risk to human health or the environment. When signing TSCA into law, the President stated that, "[TSCA] closes a gap in our current array of laws to protect the health of our people and the environment." He spoke of the various mandates of current environmental statutes and concluded that "none of the existing statutes provide(s) comprehensive protection." This is what TSCA was designed to do.

Because of the comprehensive authority of TSCA, Congress recognized that the potential existed for duplicative regulatory action. For this reason, Section 9 of TSCA directs EPA to integrate and coordinate the various Federal activities involved with controlling toxic substances whenever regulatory action is contemplated or initiated under this Act.

There are nearly two dozen Federal statutes governing toxic substances as well as a comparable number of Federal agencies responsible for the research, regulatory, and advisory provisions of these various acts. Effective integration of toxic substances activities requires an awareness and comprehension of the many Federal statutes involved as well as an understanding of the organizational structure and relevant activities of the agencies responsible for implementing these statutes.

This document is an outgrowth of the efforts on the part of the staff of EPA's Office of Toxics Integration to develop the knowledge and expertise needed to integrate and coordinate Federal toxic substances regulatory activities. During the process of familiarizing ourselves with the relevant Federal statutes and agencies, we concluded that much of the information we had been gathering was also of interest to others. Therefore, we decided to publish the material in a readily usable format and make it available to a wider audience.

The scope of this first edition is limited to 17 offices located within 8 Federal agencies or departments which, in our judgment, have a primary role in the control of toxic substances. Becaus this field is quite new and rapidly expanding, we recognize that much of the material presented here may quickly become outdated. Therefore, it is anticipated that this document will be updated annually, and future editions will include additional agencies and statutes. We welcome any suggestions for improving and/or expanding this material.

A brief note on the format may be helpful in using this publication. The information on each office is divided into several sections. The first section describes the organization of the office and highlights those divisions, branches, etc., which are concerned with toxic substances. The second section summarizes the statutory authority for the office and briefly explains those subsections of the statute which pertain to toxics. The third section (for regulatory agencies only) highlights the regulatory development process followed by that agency. The final section briefly describes the various toxics-related programs and activities.

We have also included an Appendix which provides a graphic summary of 12 major statutes involved with controlling toxic substances. The first 3 charts in the Appendix focus on 8 categories of exposure pathways and the fourth chart summarizes the major information gathering/producing provisions of the 12 statutes.

This publication would not have been possible without the cooperation and support of staff members in the various agencies and offices covered herein. Their assistance and encouragement were instrumental in guiding the manuscript through several stages of preparation. We deeply appreciate and gratefully acknowledge this assistance.

Any comments or suggestions you may have should be directed to:

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U.S. Environmental Protection Agency
401 M Street SW.
Washington, DC 20460

Telephone (202) 755-2778

Walter W. Kovalick, Jr.
Director
Toxics Integration Staff

# Federal Agencies

# *CONSUMER PRODUCT SAFETY COMMISSION*

1111 18th St. NW.
Washington, DC 20207

Locator: 202-492-6600
Information: 301-492-6731

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Regulatory Development............page 14
Toxics-Related Activities.........page 15

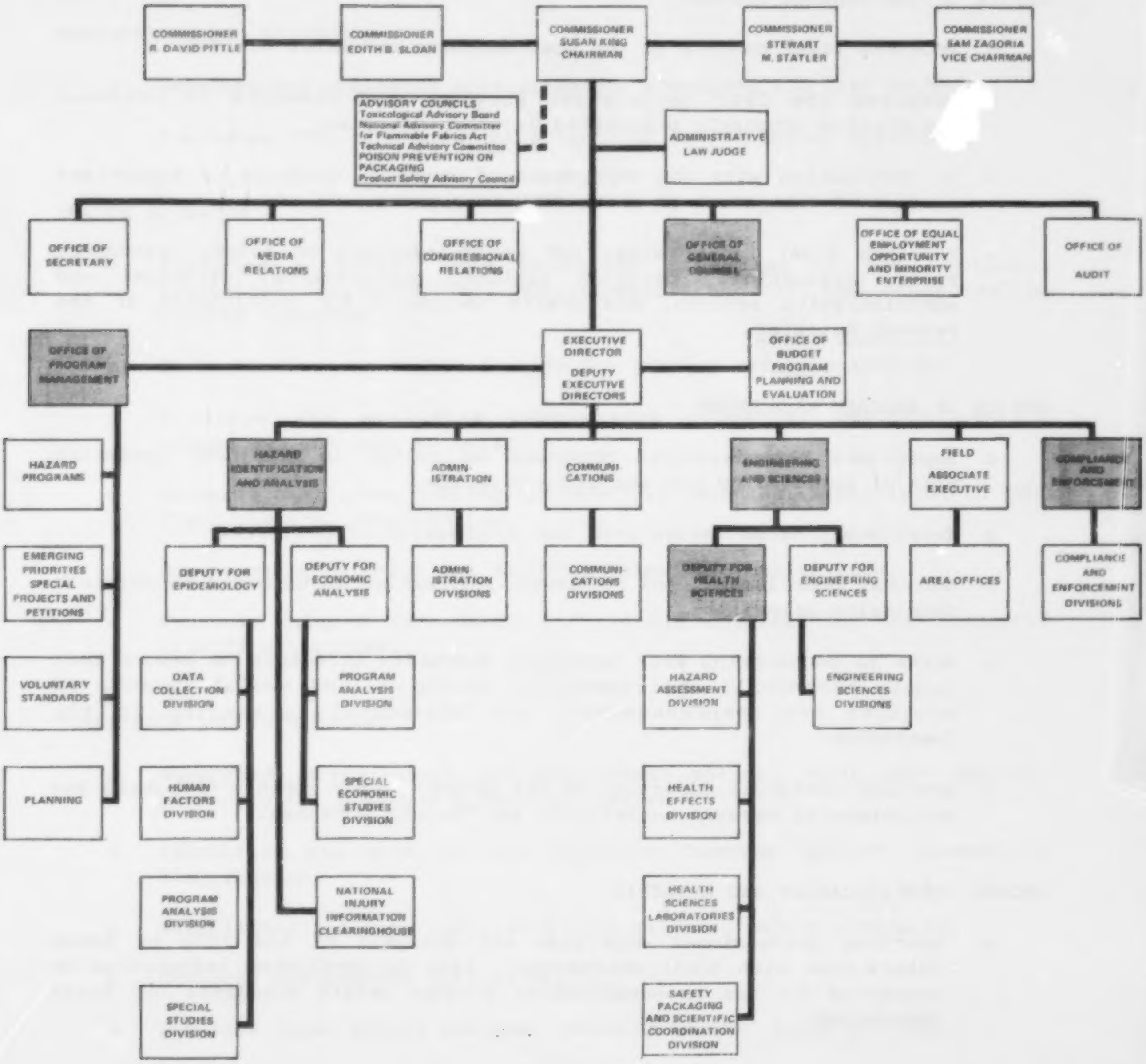
The U.S. Consumer Product Safety Commission (CPSC), established May 14, 1973 as an independent regulatory agency, is charged with reducing unreasonable risks of injury associated with consumer products. The Commission is responsible for implementing the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, the Flammable Fabrics Act, and the Refrigerator Safety Act.

The Commission issues and enforces mandatory safety standards, helps industry develop voluntary safety standards, and bans unsafe products when safety standards are not feasible. It also monitors recalls of defective products, informs and educates consumers about product hazards, conducts research and develops test methods, collects and publishes injury and hazard data, and promotes uniform product regulations by governmental units.

CPSC is headed by five Commissioners appointed by the President with the advice and consent of the Senate.

# CONSUMER PRODUCT SAFETY COMMISSION

## ORGANIZATIONAL CHART*


COMMISSIONER R. DAVID PITTLE
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COMMISSIONER SUSAN KING CHAIRMAN
COMMISSIONER STEWART M. STATLER
COMMISSIONER SAM ZAGORIA VICE CHAIRMAN
ADVISORY COUNCILS
Toxicological Advisory Board
National Advisory Committee for Flammable Fabrics Act
Technical Advisory Committee POISON PREVENTION ON PACKAGING
Product Safety Advisory Council
ADMINISTRATIVE LAW JUDGE
OFFICE OF SECRETARY
OFFICE OF MEDIA RELATIONS
OFFICE OF CONGRESSIONAL RELATIONS
OFFICE OF GENERAL COUNSEL
OFFICE OF EQUAL EMPLOYMENT OPPORTUNITY AND MINORITY ENTERPRISE
OFFICE OF AUDIT
OFFICE OF PROGRAM MANAGEMENT
EXECUTIVE DIRECTOR
DEPUTY EXECUTIVE DIRECTORS
OFFICE OF BUDGET PROGRAM PLANNING AND EVALUATION
HAZARD PROGRAMS
EMERGING PRIORITIES SPECIAL PROJECTS AND PETITIONS
VOLUNTARY STANDARDS
PLANNING
HAZARD IDENTIFICATION AND ANALYSIS
DEPUTY FOR EPIDEMIOLOGY
DEPUTY FOR ECONOMIC ANALYSIS
DATA COLLECTION DIVISION
HUMAN FACTORS DIVISION
PROGRAM ANALYSIS DIVISION
SPECIAL STUDIES DIVISION
PROGRAM ANALYSIS DIVISION
SPECIAL ECONOMIC STUDIES DIVISION
NATIONAL INJURY INFORMATION CLEARINGHOUSE
ADMINISTRATION
ADMINISTRATION DIVISIONS
COMMUNICATIONS
COMMUNICATIONS DIVISIONS
ENGINEERING AND SCIENCES
DEPUTY FOR HEALTH SCIENCES
DEPUTY FOR ENGINEERING SCIENCES
HAZARD ASSESSMENT DIVISION
HEALTH EFFECTS DIVISION
HEALTH SCIENCES LABORATORIES DIVISION
SAFETY PACKAGING AND SCIENTIFIC COORDINATION DIVISION
ENGINEERING SCIENCES DIVISIONS
FIELD ASSOCIATE EXECUTIVE
AREA OFFICES
COMPLIANCE AND ENFORCEMENT
COMPLIANCE AND ENFORCEMENT DIVISIONS

***NOTE:** A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# ORGANIZATION*

## OFFICE OF THE GENERAL COUNSEL

- Provides legal counsel to the Commissioners and staff of CPSC.
- Prepares the CPSC legislative program, and comments on relevant legislative proposals originated in other Agencies.
- In conjunction with the Department of Justice, conducts or supervises conduct of litigation in which CPSC is a party.
- Provides final legal review and recommendations on safety standards, rules, regulations, petition actions, procurements, personnel and administrative actions, and drafts documents for publication in the Federal Register.

## OFFICE OF PROGRAM MANAGEMENT

- Supervises hazard-related programs delineated in the CPSC operating plan or assigned by the Executive Director.
- Exercises program review over the progression of projects.
- Manages, coordinates, and recommends corrective adjustments to maintain Commission priorities.
- Works in conjunction with Associate Executive Directors to ensure that legal, technical, environmental, economic, and social impacts of projects are comprehensively and objectively presented to the Commission.
- Provides continual direction to all projects (for chronic chemicals and environmental hazards activities, see "Health Sciences.")

## HAZARD IDENTIFICATION AND ANALYSIS

- Provides professional expertise and analysis of the role of human interaction with toxic substances. Aids in developing information on scenarios for use in establishing product safety standards for toxic substances.

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*Note: Only those offices which customarily have dealt with toxics-related issues are described here.

- Supervises technical policy, technical quality and productivity, planning input, and review.

- Collects injury data and prepares injury data analysis to identify hazards or hazardous patterns, human factor analysis, economic impact analysis of remedial regulations, environmental assessments, and environmental impact statements.

- Collects data on the chemical ingredient of consumer products.

## ENGINEERING AND SCIENCES

- Develops and evaluates product safety standards and test methods.

- Furnishes CPSC with relevant scientific and technical expertise.

## HEALTH SCIENCES

- Provides scientific and technical expertise in the chemical, biological, toxicological, physiological, medical, and other health-related sciences.

- Collects data and assesses needs for product safety standards.

- Develops and evaluates performance criteria, quality control standards, and test methods.

- Conducts compliance testing and provides technical supervision to CPSC field chemical laboratories.

- Serves as Secretariat for National Poison Prevention Week.

- Provides program management for chronic chemical and environmental hazards activities.

## COMPLIANCE AND ENFORCEMENT

- Supervises surveillance and enforcement policy, legal case quality, productivity, planning input, and review.

- Identifies and acts on any defective consumer product already in distribution.

- Establishes industry compliance with existing safety standards.

- Conducts enforcement litigation.

- Provides legal advice and case guidance to CPSC field offices.

- Participates in the development of standards prior to promulgation.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Chairman | 202-634-7740 | Room 800<br>1111 18th St. NW.<br>Washington, D.C. 20207 |
| Executive Director | 301-492-6550 | Room 436<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Secretary of CPSC | 202-634-7770 | Room 317<br>1111 18th St. NW.<br>Washington, D.C. 20207 |
| Office of General Counsel | 202-634-7770 | Room 528<br>1111 18th St. NW.<br>Washington, D.C. 20207 |
| Office of Program Management | 301-492-6557 | Room 426<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Hazard Identification and Analysis | 301-492-6567 | Room 600-B<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Engineering and Sciences | 301-492-6494 | Room 735<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Deputy for Health Sciences | 301-492-6957 | Room 700<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Compliance and Enforcement | 301-492-6621 | Room 240<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |
| Interagency Liaison | 301-492-6731 | Room 304<br>5401 Westbard Ave.<br>Bethesda, MD 20207 |

### REGIONAL AND FIELD OFFICES

| | | |
|---|---|---|
| CPSC Atlanta Area Office | 1330 West Peachtree St., NW.<br>Atlanta, GA 30309 | 404-881-2231<br>FTS: 8-257-2231 |

| | | |
|---|---|---|
| CPSC Boston<br>Area Office | Room 1607<br>100 Summer St.<br>Boston, MA 02110 | 617-223-5576<br>FTS: 8-223-5576 |
| CPSC Chicago<br>Area Office | Room 2945<br>230 South Dearborn St.<br>Chicago, IL 60604 | 312-353-8260<br>FTS: 8-353-8260 |
| CPSC Cleveland<br>Area Office | Plaza Nine Bldg.<br>Room 520<br>55 Erieview Plaza<br>Cleveland, OH 44114 | 216-522-7160<br>FTS: 8-293-7160 |
| CPSC Dallas<br>Area Office | Room 1610<br>11 Commerce St.<br>Dallas, TX 75242 | 214-767-0841<br>FTS: 8-729-0841 |
| CPSC Denver<br>Area Office | Guaranty Bank Bldg.<br>Suite 938<br>817 17th St.<br>Denver, CO 80202 | 303-837-4795<br>FTS: 8-327-4795 |
| CPSC Kansas City<br>Area Office | Midland Bldg.<br>Suite 1000<br>1221 Baltimore Ave.<br>Kansas City, MO 64105 | 816-374-3151<br>FTS: 8-758-3151 |
| CPSC Los Angeles<br>Area Office | Suite 1100<br>3660 Wilshire Blvd.<br>Los Angeles, CA 90010 | 213-688-7272<br>FTS: 8-798-7272 |
| CPSC New York<br>Area Office | 6 World Trade Center<br>6th Floor<br>Vesey St.<br>New York, NY 10048 | 212-264-2266<br>FTS: 8-264-1134 |
| CPSC Philadelphia<br>Area Office | 10th Floor<br>400 Market St.<br>Philadelphia, PA 19106 | 215-597-9362<br>FTS: 8-597-9362 |
| CPSC San Francisco<br>Area Office | U.S. Customs House<br>Room 416<br>555 Battery Street<br>San Francisco, CA 94111 | 415-556-1819<br>FTS: 8-556-1819 |
| CPSC Seattle<br>Area Office | 3240 Federal Bldg.<br>915 Second Ave.<br>Seattle, WA 98174 | 206-442-5276<br>FTS: 8-399-5276 |
| CPSC Twin Cities<br>Area Office | Metro Square<br>Suite 580<br>7th & Robert<br>St. Paul, MN 55101 | 612-725-7781<br>FTS: 8-725-7781 |

# STATUTORY AUTHORITIES

## Consumer Product Safety Act

### Public Law 92-573 15 U.S.C. §§ 2051-2063

The Consumer Product Safety Act (CPSA) grew out of the need for a unified and comprehensive approach to the regulation of the safety of consumer products. Prior to 1973, several agencies had authority over different aspects of consumer product safety. The Consumer Product Safety Act established the Consumer Product Safety Commission as an independent regulatory commission and also gave the Commission responsibility for the Federal Hazardous Substances Act (FHSA), the Poison Prevention Packaging Act (PPPA), the Flammable Fabrics Act (FFA), and the Refrigerator Safety Act (RSA).

The purposes of the Act are to assist consumers in evaluating the comparative safety of consumer products, to protect the public against unreasonable risks of injury associated with consumer products, to develop uniform safety standards for consumer products, to minimize conflicting State and local regulations, and to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 5(a) | Requires Commission to maintain an injury information clearinghouse on hazards associated with consumer products. |
| sec. 6 | Provides procedures for disclosure of information obtained by the Commission. |

| | |
|---|---|
| sec. 7 | Provides authority to promulgate consumer product safety standards in order to prevent risks of injury associated with consumer products. The standard can consist of requirements as to the various aspects of a consumer product such as packaging, composition, design, or requirements for labeling with clear warnings or instructions. |
| sec. 8 | Provides authority for banning consumer products that present an unreasonable risk of injury. |
| sec. 9 | Details administrative procedures for promulgation of consumer product safety rules. |
| sec. 10 | Allows the public to petition the Commission for a consumer product safety rule. |
| sec. 12 | Empowers the Commission to take immediate action against imminently hazardous consumer products. |
| sec. 13 | Provides for the promulgation of rules concerning new consumer products. |
| sec. 14 | Requires manufacturers of consumer products to certify conformity to CPSC safety standards. Allows CPSC to require the use and prescribe the form and content of labels. |
| sec. 15 | Authorizes the Commission to require manufacturers of hazardous products to take certain actions (notification and repair, replacement, or refund). |
| sec. 30(d) | Gives the Commission the ability to regulate risks of injury under this act rather than FHSA, PPPA, or FFA, if the Commission finds it to be in the public interest. |

### Regulatory Options Available Under Statute

- Assisting in voluntary standards development
- Enacting mandatory standards
- Removing or recalling of products
- Banning

## Federal Hazardous Substances Act

### Public Law 86-613 15 U.S.C. §§ 1261-74

The Federal Hazardous Substances Act (FHSA) was enacted in 1960. It began as a labeling law. The original law established definitions for toxic, corrosive, irritant, flammable, and radioactive substances. Materials that met the definitions were required to bear cautionary labeling. Subsequently, two provisions were added that permit the banning of certain household substances. A hazardous household substance can be banned by regulation under FHSA if the Commission decides that the degree or nature of the hazard involved warrants removal of such substance from interstate commerce because no cautionary labeling that could be required under the Act would be adequate to address the hazard. If the substance is deemed to pose an imminent hazard to public health, the Commission can prevent its distribution in interstate commerce upon publication of a Federal Register notice of imminent hazard pending the completion of the rulemaking proceedings.

Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 2 | Establishes definitions for hazardous substances and requires substances which meet the definitions to be labeled. Authorizes banning of hazardous substances where the nature and degree of the hazard is such that no possible labeling would be adequate to protect the public health and safety. |
| sec. 3 | Allows the Commission to declare products hazardous, to require special labeling, and to ban imminent hazards. |
| sec. 4 | Outlines illegal acts under the Federal Hazardous Substances Act. |
| sec. 5-9 | Gives the Commission authority to invoke penalties, seize products, hold hearings, issue injunctions, and subpoena witnesses. |
| sec. 10 | Gives the Commission authority to promulgate regulations for efficient enforcement of this act. |
| sec. 15 | Requires the repurchase of banned hazardous substances up the chain of distribution to manufacturers. |
| sec. 20 | Establishes the Toxicological Advisory Board to give scientific and technical advice to the Commission. |

Regulatory Options Available Under Statute

- Declaring products to be hazardous substances which must be labeled in accordance with the Act
- Requiring special labeling for hazardous household substances
- Banning hazardous household substances
- Repurchasing of banned hazardous substances up the chain of distribution

## Poison Prevention Packaging Act

## Public Law 91-601 15 U.S.C. §§ 1471-1476

Administration of the Poison Prevention Packaging Act of 1970 (PPPA) was transferred to the Commission from the Food and Drug Administration in 1973. Under this Act, the Commission can establish standards for special packaging of household substances in order to protect children from handling, using, or ingesting hazardous substances. Products that can be regulated under PPPA include products covered by the Federal Hazardous Substances Act as well as food, drugs, cosmetics, and fuels in portable containers.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 3 | Gives the Commission authority to establish special packaging standards for hazardous household substances. |
| sec. 4 | Authorizes manufacturers to supply noncomplying products in a single size especially for use by elderly or handicapped persons. |
| sec. 5 | Establishes requirements for proceedings to issue, amend, or repeal a regulation prescribing a standard. |
| sec. 6 | Establishes the Technical Advisory Committee to assist the Commission in implementing the Act. |

### Regulatory Options Available Under Statute

- Establishing special packaging standards
- Establishing exemptions from special packaging standards for particular substances

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

1. Identification of "candidate product" for regulatory development:
   - o Internal--data gathering and analysis.
   - o External--Commission receives petition. Notification of hazardous product by manufacturer (Section 15, CPSA).
2. Development of strategy:
   - o Conduct relevant analyses.
   - o Satisfy Section 9 (CPSA) requirements--assessment of economic impact of proposed regulation; must show that regulation will reduce "unreasonable risk."
3. Preparation of briefing package by Program Manager and drafting of proposed regulation by the Office of General Counsel.
4. Review of briefing package and proposed regulation by agency staff.
5. Revision of briefing package and proposed regulation.
6. Approval of proposal by Commission.
7. Review of public comments, development of final regulation, approval by Commission, promulgation of final rule, and commencement of enforcement activities.

## EXISTING REGULATIONS

| | |
|---|---|
| Consumer Product Safety Act | 16 CFR 1015-1402 |
| Federal Hazardous Substances Act | 16 CFR 1500-1512 |
| Poison Prevention Packaging Act | 16 CFR 1700-1704 |

# TOXICS-RELATED ACTIVITIES*

The Consumer Product Safety Commission has two programs which address toxic substances: The Acute Chemical Hazards program and the Chronic Chemical Hazards program.

The Acute Chemical Hazards Program is concerned with products that have immediate injurious effects. Such hazards have long been recognized, and Congress has given the Commission specific powers to deal with them. Under the Poison Prevention Packaging Act (PPPA), the Commission may require child-resistant packaging for household substances which present serious hazards. In addition, the Federal Hazardous Substances Act (FHSA) not only sets baseline labeling requirements for hazardous household products and allows the Commission to require additional cautionary labeling if necessary, but also allows the Commission to ban products altogether if labeling is inadequate to protect the public. Special packaging requirements are now in effect for 14 categories of hazardous substances.

The Chronic Chemical Hazards program is concerned with reducing consumer exposure to products which cause or contribute to adverse health effects whose appearance occurs some time after exposure to a substance. The program is designed to enable the agency to identify the substances and exposures of concern, evaluate them and their risks, set priorities, and determine the regulatory and nonregulatory methods for reducing or eliminating the risks.

---

*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances-Toxics Integration staff.

A step-by-step approach has been developed for identifying candidates for regulation. Usually chemicals are identified as candidates for screening through test results or toxicity data published by government, industry, the research community, and others. Typical sources have been the National Cancer Institute (NCI) and the International Agency for Research in Cancer (IARC). The screening process, involving a pipeline of increasingly finer screens, asks whether the chemical has toxic properties (such as an ability to cause cancer, mutation, or birth defects); whether it is used in consumer products; whether the uses are within CPSC's jurisdiction; whether the uses may result in consumer exposure; whether the exposure results in absorption of the chemical; and whether the exposure is widespread, of long duration, or intense. This step-by-step process is designed to enable the Commission to set priorities for action among the thousands of chemicals in use today.

In addition to looking at suspect chemicals, the Commission looks at product categories which may result in widespread consumer exposure. The Commission then asks what the products contain, whether the contents have been tested for potential toxic effects by any Government agency, whether industry has tested the contents, and, as appropriate, whether testing needs to be conducted to measure the safety of an ingredient suspected to be hazardous.

Initially, during Fiscal Year 1979, the program focused on carcinogens; during Fiscal Year 1980 and beyond, the program will continue to emphasize carcinogens while paying careful attention to chemicals that cause other chronic health problems, particularly birth defects and neurological dysfunctions.

Brief descriptions of the substances currently included in these two programs are provided below.

## Asbestos

The Consumer Product Safety Commission has banned consumer garments containing asbestos, tape joint compounds containing asbestos, and artificial fireplace embers of asbestos. In May 1978 the Commission initiated actions against hand-held hairdryers containing asbestos and voluntary corrective action was undertaken by the industry to refit, exchange, or refund the purchase price of hairdryers containing asbestos. An Advanced Notice of Proposed Rulemaking has been published commencing an investigation of asbestos use in consumer products and seeking comment on CPSC possible regulatory approaches to asbestos.

CPSC is closely coordinating these regulatory activities with the Environmental Protection Agency and the other IRLG agencies to ensure maximum effectiveness and to minimize reporting burdens on industry.

## Benzene

The Commission on May 19, 1978, proposed a rule to regulate consumer products containing benzene as an intentional ingredient or as a contaminant. The Commission took this action because of information indicating that exposure to benzene may cause blood disorders, including leukemia, and chromosomal abnormalities. Due to complex issues raised by the proposed rule, the Commission has extended to October 13, 1980, the time in which it must issue a final rule or withdraw the proposed regulation.

The staff has conducted a limited market survey to update information on the benzene content of consumer products, is assessing the results of animal teratology studies, and is conducting a study of the air levels of benzene produced by the use of consumer products containing benzene. The Commission has published a general order requiring firms that have used benzene as an ingredient in their products since January 1, 1979, to report that use to the Commission. Regulatory activities with other Federal agencies are being coordinated through the IRLG Benzene workgroup.

## Formaldehyde

The Commission has received over 1,000 complaints to date dealing primarily with formaldehyde release in the home from urea-formaldehyde foam (UFF) insulation. A recent report of the possible carcinogenicity in test animals from formaldehyde vapors in animals has heightened the Commission's concern. The Commission is currently gathering and evaluating existing data on formaldehyde toxicity and chemistry. It is also waiting for the results of studies it has implemented with the Department of Energy (to determine the factors involved in formaldehyde off-gassing from UFF). The Commission staff has recommended that the Commission propose a regulation that would require manufacturers of UFF insulation to provide information to customers concerning the release of formaldehyde from the product. The Commission intends to prepare recommendations for regulatory options for UFF insulation by September 1980. Regulatory activities will be coordinated with other Federal agencies through the IRLG Formaldehyde Task Group which is chaired by CPSC's Dr. Andrew Ulsamer.

## Benzidine-Based and Benzidine-Derived Dyes

On October 18, 1978, the Commission was petitioned by Artist-Craftsmen of New York, Inc. et al., to issue a rule under Section 8 of the CPSA banning benzidine-based and benzidine-derived dyes. The petitioners state that the dyes present a risk of bladder cancer to humans and can be inhaled, ingested, and absorbed through the skin during consumer use.

The staff is evaluating data on the metabolism, epidemiology, carcinogenicity, mutagenicity, and exposure to these dyes. Retail dye packet samples are being analyzed for the presence of benzidine, o-tolidine, and o-dianisidine and of dyes based upon these compounds. Experimental studies are being conducted on the skin absorption and metabolic fate of the benzidine-based dye group. CPSC is coordinating regulatory activities with other Federal agencies through the IRLG Benzidine Task Group.

## Chemical Room Deodorizers

This project was initiated by the staff in early Fiscal Year 1979 to investigate potential toxic effects from chronic exposure to low levels of chemical substances in room deodorizers. The staff plans to conduct a study to identify the chemicals used in these products and will conduct studies of the reproductive effects of at least one of the most popular formulations.

## Carbon Monoxide

In the course of developing a consumer product safety standard to reduce consumer exposure to toxic gases from unvented gas-fired space heaters, an additional issue of potential toxic effects from chronic exposure to low levels of carbon monoxide from a variety of sources was identified. The staff is conducting a comprehensive search and review of current information. A study is planned to measure actual levels of carbon monoxide produced by unvented gas-fired space heaters and other fuel-burning appliances. The health effects of those levels will be evaluated.

## Chlorofluorocarbons

During 1979 the ban on nonessential uses of fully halogenated chlorofluorocarbons in propellants in aerosols became fully effective. The Interagency Chlorofluorocarbon Workgroup (CPSC, EPA, FDA et al.) continues its work to develop regulatory options for other nonaerosol propellant uses of chlorofluorocarbons. In addition, the study has opened a broader issue related to other potentially toxic gases which may be present in the indoor environment as a result of emissions from consumer products.

## Hydrocarbon Propellants

The Commission has directed the staff to gather and evaluate data and information on potential health effects of hydrocarbon propellants in aerosol consumer products. The staff is examining the consumer safety implications of the switchover from chlorofluorocarbons (CFCs) to hydrocarbon propellants. Consumer products subject to CPSC's jurisdiction have been identified and formulation data collected. The Commission staff plans to evaluate toxicity and exposure data for hydrocarbon propellants.

## Labeling of Aerosol Propellant Ingredients

Several years ago, the Commission determined that aerosol consumer products containing vinyl chloride monomer propellants potentially presented an unreasonable carcinogenic risk to the public. Subsequently, products containing these chemicals were banned and the Commission directed the staff to consider drafting a proposed rule requiring labeling of aerosol products with the composition of substances used as propellants. The staff and Commissioners will consider this issue further.

## Lead

Lead has been banned from paints at levels in excess of 0.06 percent since 1978. Subsequently, both consumer complaints and reports in the scientific literature have alerted CPSC to the use of lead in consumer products such as decorated glassware, gift wrap paper, and wearing apparel. The staff is assessing the bioavailability of lead from such products and estimating potential exposure levels in order to develop regulatory options.

## Hexane

The Commission received a petition in July 1979, to ban marketing, dissemination, distribution, and sale of products containing n-hexane. While the petition was formally denied, the Commission has instructed the staff to evaluate the toxicity of n-hexane, to obtain technical data on levels of consumer exposure to products containing n-hexane, and to provide an assessment of potential hazard. The staff is also evaluating the possible additive effects of chemical agents such as methyl ethyl ketone and methyl butyl ketone which are frequently associated with n-hexane.

## Art Hazards

The major substances to which artisans are exposed are: pigments, solvents, lead, and other heavy metals. During the past 8 months the Commission has completed a study to identify 1) firms and industries in the area of arts and crafts; 2) art and craft products; and, 3) chemicals and materials used in these products and the potential health effects of these chemicals. The study provides baseline data should the Commission decide to take future regulatory action in the area of art products.

# COUNCIL ON ENVIRONMENTAL QUALITY

722 Jackson Place NW.
Washington, D.C. 20006

Locator: 202-395-5700
Information: 202-395-5770

Organization....................page 23
Statutory Authorities..........page 29
Toxics-Related Activities......Page 32

The Council on Environmental Quality (CEQ) is the policy advisory body for environmental matters in the Executive Office of the President. Created by the National Environmental Policy Act of 1969 (NEPA), its principal responsibilities are to oversee the implementation of that Act and to develop and advise the President on national policies and programs affecting environmental quality. Additional responsibilities were provided by the Environmental Quality Improvement Act of 1970, Executive Order 11514, as amended by Executive Order 11991, and Reorganization Plan No. 1 of 1977.

CEQ's general charge includes:

- Developing and recommending national policies which foster and promote improvement of environmental quality, including review and assessment of the effectiveness of existing and proposed Federal facilities, program policies, and activities which affect environmental quality, development of the President's environmental message to Congress, and assisting in development of the President's environmental legislation programs,

- Assisting Federal agencies in coordinating programs and activities which affect, protect, and improve environmental quality. This includes promulgating and maintaining regulations implementing the procedural provisions of NEPA and the referral process under Section 309 of the Clean Air Act, overseeing the NEPA process, developing guidelines for evaluating environmental impacts of Federal actions, and developing and promoting means to prevent or reduce adverse effects of such actions,

- Gathering and analyzing information concerning conditions and trends in the quality of the environment, including the development and maintenance of UPGRADE, developing special studies and analyses on environmental quality and health, and assisting the President in the preparation of the annual environmental quality report to the Congress.

The Council's specific statutory responsibilities include:

- Issuing regulations to implement the procedural provisions of NEPA including regulations for the preparation of environmental impact statements (EIS) for major Federal actions which significantly affect the quality of the human environment,

- Resolving conflicts which are referred to the Council by agencies under Section 102(2) of NEPA and Section 309 of the Clean Air Act,

- Preparing for transmittal by the President to the Congress an annual report setting forth conditions and trends in environmental quality.

- Developing and maintaining the National Oil and Hazardous Materials Pollution Contingency Plan under Section 311 of the Clean Water Act.

CEQ addresses a wide variety of environmental policy issues, including those pertaining to evaluation of the health effects of exposure to toxic substances, and program and/or regulatory strategies for their control. CEQ has a long and active involvement in the toxic substances and environmental health fields. CEQ prepared the first Toxic Substances Control Act (TSCA) legislation proposed to Congress by the President in 1970 and participated in events leading to the passage of TSCA in 1976. CEQ has been involved in the implementation of TSCA, participating in the development and review of various program and budget issues. Pursuant to the President's 1977 Environmental Message charging CEQ with developing recommendations to address gaps and overlaps in information, research, and regulation of Federal programs dealing with toxic substances, CEQ chairs the Toxic Substances Strategy Committee, whose final report to the President will be published in May, 1980. CEQ chairs the Interagency Task Force on Environmental Data and Monitoring which is designed to develop effective and systematic toxics data monitoring capabilities of the Federal Government. CEQ cochairs (with EPA) the Interagency Toxic Substances Data Committee, a permanent interagency committee formed pursuant to Section 10(b) of the Toxic Substances Control Act and other legislative and executive mandates. The Data Committee is charged with the responsibility of developing an integrated data network to support Government in toxics research and regulation. The Council is a statutory member of the Interagency Testing Committee formed pursuant to Section 4 of TSCA and participates in other interagency committees addressing toxics research and regulation. In addition to TSCA-related activities, the Council reviews toxics-related budget, policy, and program issues, including those relating to pesticides, occupational health, hazardous waste, consumer products, drugs, pollution, and environmental health research. The Council also has been active in promoting Federal support for the development and use of integrated pest management and in analyzing the economic benefits of toxic substances regulations.

The Council on Environmental Quality operates on a policy level to assist Federal agencies in program development and implementation and to provide environmental advice to the President. The Council has a toxic substances and environmental health staff to direct this effort. The Council does not issue "toxics regulations." Therefore, a regulatory development section is not included for this agency.

The Council is organized into 11 functional components:

- Executive Office
- Public and Congressional Affairs
- General Counsel
- Administrative Office
- Environmental Data and Monitoring
- Land Use and Wildlife
- Energy and Resource Recovery
- Economics and Pollution Control
- International and Global Affairs
- Environmental Health and Toxic Substances
- Public Lands and Water Resources

The principal staff component involved in toxic substances matters is the Environmental Health and Toxic Substances staff. Other staff units with additional responsibility include General Counsel, Environmental Data and Monitoring, International and Global Affairs, and Economics and Pollution Control.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

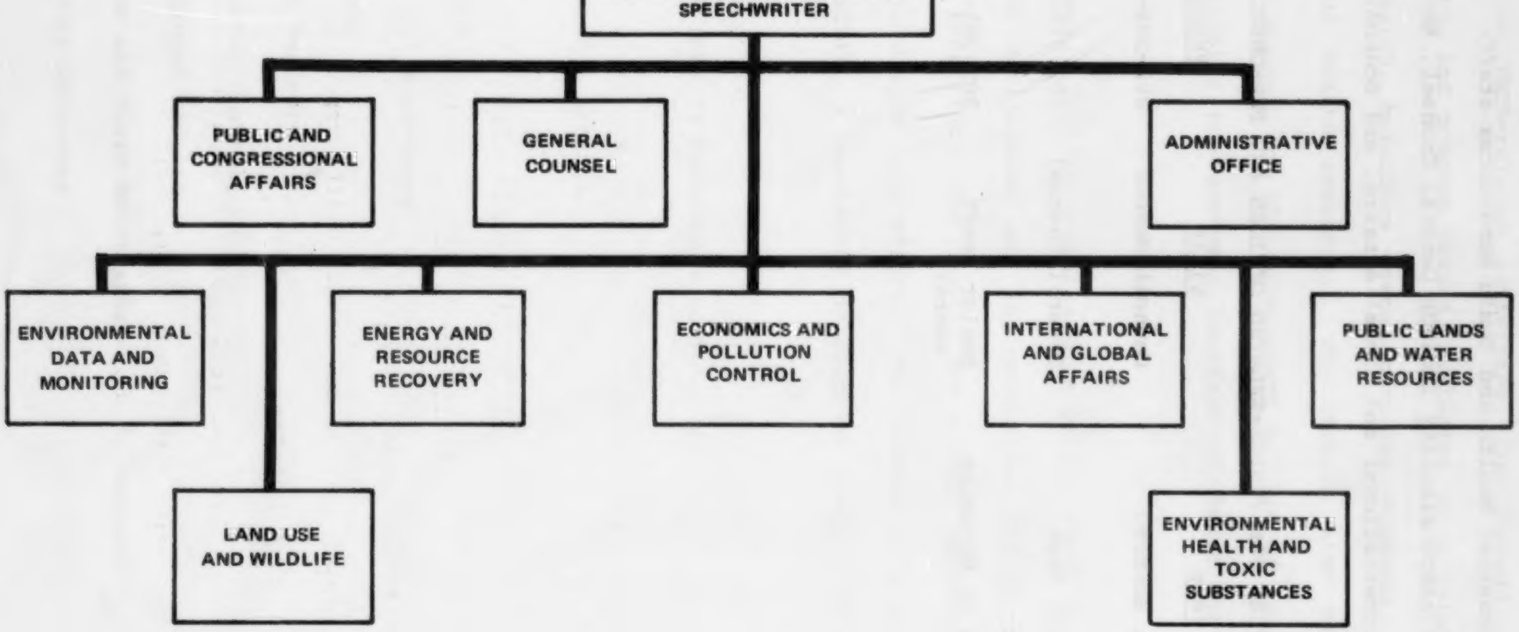
| Name | Title | Phone* | Area of focus |
|---|---|---|---|
| Robert Harris | Council Member | 202-395-5700 | Environmental health and toxic substances |
| Nicholas Yost | General Counsel | 202-395-5750 | Environmental impact statements |
| Robert B. Nicholas | Senior Staff Member | 202-395-4980 | Environmental health and toxic substances |

---

*All mail should be addressed to the Washington, D.C., address.

# COUNCIL ON ENVIRONMENTAL QUALITY

## ORGANIZATIONAL CHART


EXECUTIVE OFFICE
CHAIRMAN
MEMBERS
EXECUTIVE DIRECTOR
DEPUTY EXECUTIVE DIRECTOR
SPEECHWRITER
PUBLIC AND CONGRESSIONAL AFFAIRS
GENERAL COUNSEL
ADMINISTRATIVE OFFICE
ENVIRONMENTAL DATA AND MONITORING
ENERGY AND RESOURCE RECOVERY
ECONOMICS AND POLLUTION CONTROL
INTERNATIONAL AND GLOBAL AFFAIRS
PUBLIC LANDS AND WATER RESOURCES
LAND USE AND WILDLIFE
ENVIRONMENTAL HEALTH AND TOXIC SUBSTANCES

# STATUTORY AUTHORITIES

## National Environmental Policy Act

### Public Law 91-190    42 U.S.C. §§ 4341-4347

The Council on Environmental Quality was established in 1970 under Section 202 of this Act. NEPA establishes a national policy of using all practicable means to prevent damage to the environment. It charges Federal agencies with the duty of analyzing the potential impact of a proposed action and its alternatives, and to consider these impacts and the goals set forth in NEPA in the course of their decisionmaking. The duties and functions of CEQ are spelled out in Section 204 of the Act. Among other responsibilities, the Council must review and appraise the various programs and activities of the Federal Government to determine their consistency with NEPA's goals.

## Environmental Quality Improvement Act of 1970

### Public Law 91-224    42 U.S.C. §§ 4371-4374

The Environmental Quality Improvement Act of 1970 created an Office of Environmental Quality to provide staff support to CEQ. It brought more funding and responsibilities to CEQ. It specified that CEQ should appraise Federal programs and policies, review monitoring, evaluate the effects of technology, and assist Federal agencies in the development of environmental standards.

## Toxic Substances Control Act

## Public Law 94-469 15 U.S.C. § 2601

CEQ is one of eight statutory members of the Interagency Testing Committee. This Committee was established under Section 4(e) of the Act to recommend (to the Administrator of EPA) chemical substances and mixtures for priority consideration when promulgating regulations under section 4(a). In addition, CEQ cochairs, with EPA, the Interagency Toxic Substances Data Committee and has been directed under Section 25(b) to coordinate a study on the development of a chemical information network.

## Health Services Research, Health Statistics, and Health Care Technology Act

## 42 U.S.C. § 242

CEQ's responsibilities under this Act include participation in an ongoing study of the health costs of pollution and assistance in the establishment of guidelines for the collection of health information and statistics in order to improve coordination of environmental and health studies.

## Executive Order 11514 (March 5, 1970) as amended by Executive Order 11991 (May 24, 1977), and Reorganization Plan No. 1 of 1977

This Order and Plan empowers the Council to recommend to the President and to Federal agencies priorities in environmental programs. It gives the Council responsibility for advising and assisting the President and Federal agencies in achieving international cooperation for dealing with environmental problems, under the foreign policy guidance of the Secretary of State. It also authorizes the Council to issue regulations binding on all Federal agencies to implement the procedural provisions of the National Environmental Policy Act.

## Environmental Effects Abroad of Major Federal Actions, January 5, 1979

## Executive Order 12114

This Order requires that environmental review procedures be established for major international Federal actions including those involving the export of a product, or a facility whose products, emissions, or effluents are prohibited or regulated because their toxic effects on the environment create a serious public health risk.

## Assignment of Functions Under Section 311 of the Clean Water Act (Formerly Federal Water Pollution Control Act), August 7, 1973

## Executive Order 11735

This Order delegates authority to various agencies of the Federal Government to deal with actual or threatened discharges of oil or hazardous substances in waterways, from both onshore and offshore facilities. The Environmental Protection Agency and the U.S. Coast Guard are empowered to exercise the authority of the President in enforcing regulations issued pursuant to this Order. The Council on Environmental Quality is the designated coordinating agency for the preparation of the "National Oil and Hazardous Materials Pollution Contingency Plan" (see 40 CFR 150 and 44 FR 28196).

# TOXICS-RELATED ACTIVITIES

Program Description

The Council's toxics program is policy oriented. CEQ conducts studies on an ad hoc basis, develops programs for interagency coordination and makes recommendations for executive action. Among the current studies being conducted by the Council are the following: cancer incidence and mortality trends, human reproductive hazards from environmental pollution, and ground water contamination from hazardous waste disposal.

# DEPARTMENT OF AGRICULTURE

14th Street and Independence Avenue SW.
Washington, D.C. 20250

Locator: 202-447-5781
Information: 202-447-2791

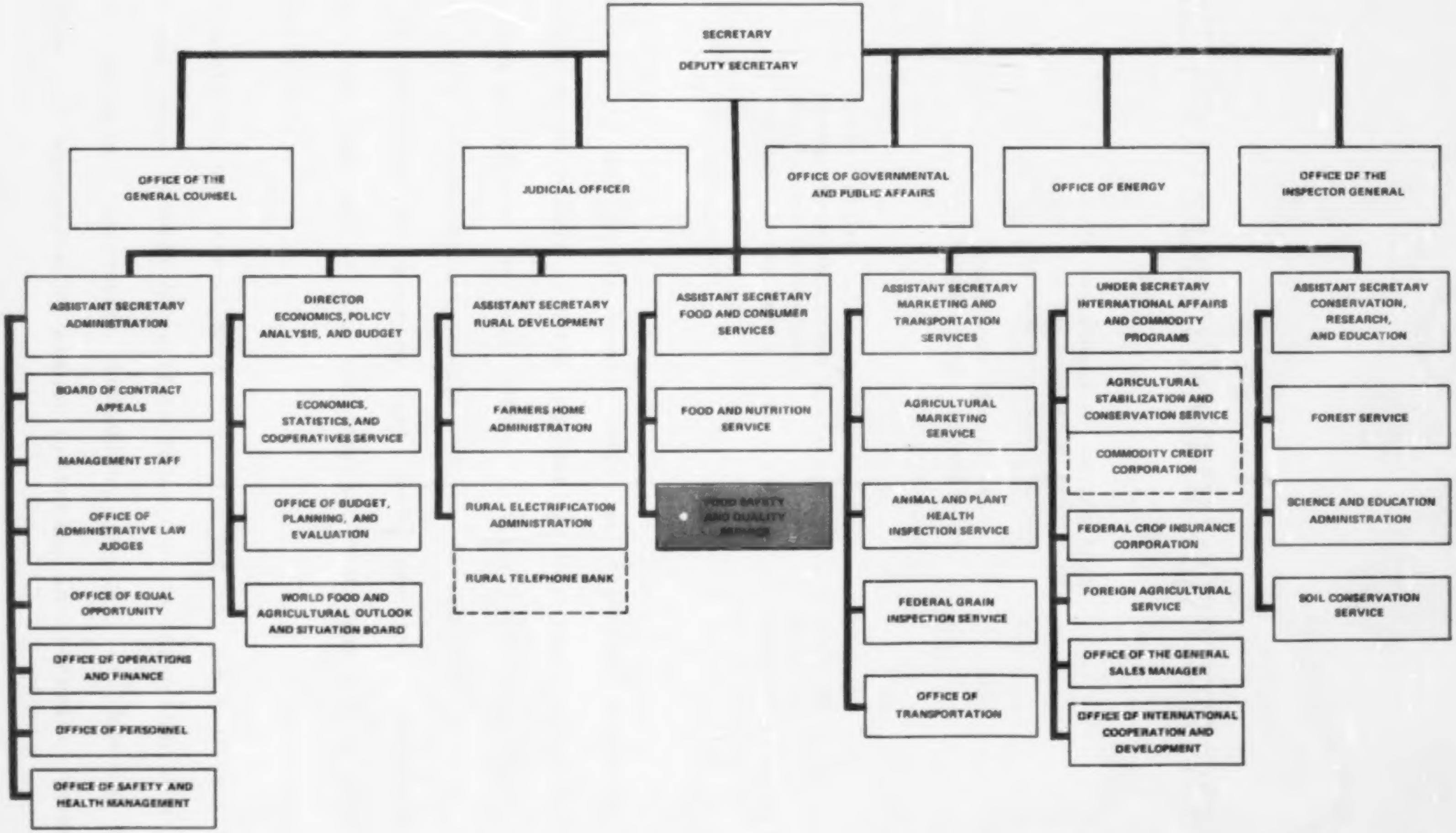
The Department of Agriculture (USDA) serves all Americans. It works to improve and maintain farm income and to develop and expand markets abroad for agricultural products. The Department helps to curb poverty, hunger, and malnutrition. It works to enhance the environment and to maintain our production capacity by helping landowners protect the soil, water, forests, and other natural resources. Rural development, credit, and conservation programs are key resources for carrying out national growth policies. USDA research findings directly or indirectly benefit all Americans. The Department, through inspection and grading services, safeguards and assures standards of quality in the daily food supply.

The act of Congress, approved May 15, 1862, created the Department of Agriculture, which was administered by a Commissioner of Agriculture until 1889. By act of February 9, 1889, the powers and duties of the Department were enlarged. The Department was made the eighth executive department in the Federal Government, and the Commissioner became the Secretary of Agriculture.

This publication focuses on the responsibilities and activities of the Food Safety and Quality Service (FSQS) located within the Department's Food and Consumer Services Office.

# DEPARTMENT OF AGRICULTURE

## ORGANIZATIONAL CHART*


SECRETARY
DEPUTY SECRETARY
OFFICE OF THE GENERAL COUNSEL
JUDICIAL OFFICER
OFFICE OF GOVERNMENTAL AND PUBLIC AFFAIRS
OFFICE OF ENERGY
OFFICE OF THE INSPECTOR GENERAL
ASSISTANT SECRETARY ADMINISTRATION
BOARD OF CONTRACT APPEALS
MANAGEMENT STAFF
OFFICE OF ADMINISTRATIVE LAW JUDGES
OFFICE OF EQUAL OPPORTUNITY
OFFICE OF OPERATIONS AND FINANCE
OFFICE OF PERSONNEL
OFFICE OF SAFETY AND HEALTH MANAGEMENT
DIRECTOR ECONOMICS, POLICY ANALYSIS, AND BUDGET
ECONOMICS, STATISTICS, AND COOPERATIVES SERVICE
OFFICE OF BUDGET, PLANNING, AND EVALUATION
WORLD FOOD AND AGRICULTURAL OUTLOOK AND SITUATION BOARD
ASSISTANT SECRETARY RURAL DEVELOPMENT
FARMERS HOME ADMINISTRATION
RURAL ELECTRIFICATION ADMINISTRATION
RURAL TELEPHONE BANK
ASSISTANT SECRETARY FOOD AND CONSUMER SERVICES
FOOD AND NUTRITION SERVICE
FOOD SAFETY AND QUALITY SERVICE
ASSISTANT SECRETARY MARKETING AND TRANSPORTATION SERVICES
AGRICULTURAL MARKETING SERVICE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
FEDERAL GRAIN INSPECTION SERVICE
OFFICE OF TRANSPORTATION
UNDER SECRETARY INTERNATIONAL AFFAIRS AND COMMODITY PROGRAMS
AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE
COMMODITY CREDIT CORPORATION
FEDERAL CROP INSURANCE CORPORATION
FOREIGN AGRICULTURAL SERVICE
OFFICE OF THE GENERAL SALES MANAGER
OFFICE OF INTERNATIONAL COOPERATION AND DEVELOPMENT
ASSISTANT SECRETARY CONSERVATION, RESEARCH, AND EDUCATION
FOREST SERVICE
SCIENCE AND EDUCATION ADMINISTRATION
SOIL CONSERVATION SERVICE

***NOTE:** A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# DEPARTMENT OF AGRICULTURE

## ORGANIZATIONAL CHART

# *THE FOOD SAFETY AND QUALITY SERVICE*

U.S. Department of Agriculture
14th and Independence Avenue SW.
Washington, D.C. 20250

Locator: 202-447-6617
Information: 202-447-7943

Organization. . . . . . . . . . . . . . . . page 40
Statutory Authorities . . . . . . . . . . . page 46
Regulatory Development. . . . . . . . . . page 50
Toxics-Related Activities . . . . . . . . page 55

The Food Safety and Quality Service (FSQS) was organized by the Secretary of Agriculture in March 1977 to bring together the Department of Agriculture's consumer programs related to food safety, quality, and procurement. The purpose of this organizational change was to develop and provide better services to consumers by assuring that foods are safe, wholesome, and nutritious, that they are of good quality, and that they are uniformly and honestly labeled.

FSQS administers the Federal Meat Inspection Act and the Poultry Products Inspection Act, which provide for uniform Federal-State inspection of all meat and poultry products. Inspection regulations require prior approval of the construction and equipment of plants operating in interstate commerce;

inspection of birds and animals before, during, and after slaughter; continuous inspection of all processing operations; and prior approval of labels for meat and poultry products.

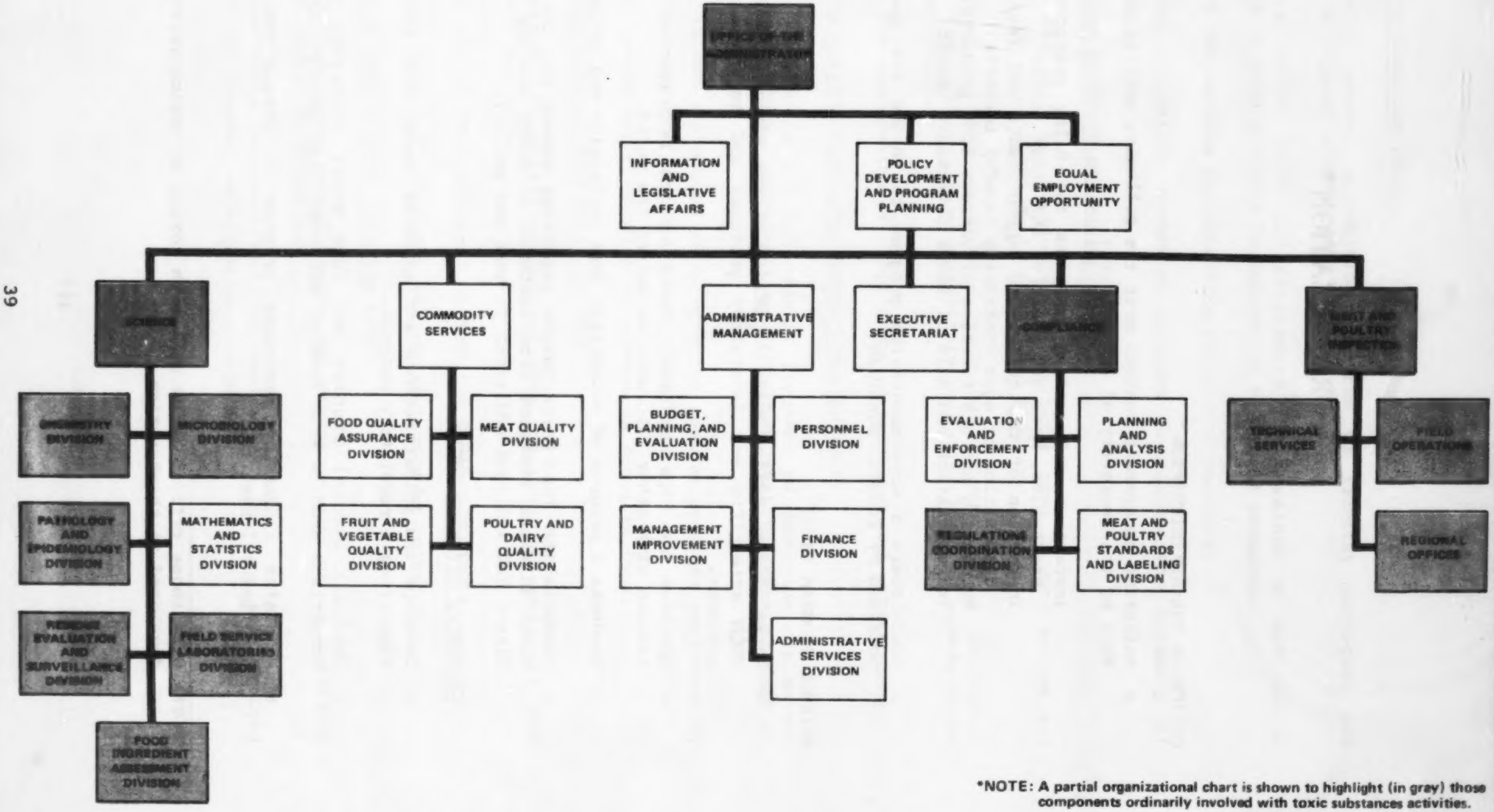
The FSQS inspection program also includes activities to guard against disease and residues in domestic and imported meat and poultry products, and monitoring activities in foreign plants handling these products for import into the United States.

In addition, FSQS participates in the regulation of toxics under two separate statutory authorities. First, FSQS may issue its own regulations as provided by both the Meat Inspection and the Poultry Products Inspection Acts for any toxic substances which may threaten to contaminate meat and poultry food supplies. Second, under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) regulates toxic substances which may be found in foods, drugs, or cosmetic products.

## U.S. DEPARTMENT OF AGRICULTURE

# FOOD SAFETY AND QUALITY SERVICE

## ORGANIZATIONAL CHART*



OFFICE OF THE ADMINISTRATOR
INFORMATION AND LEGISLATIVE AFFAIRS
POLICY DEVELOPMENT AND PROGRAM PLANNING
EQUAL EMPLOYMENT OPPORTUNITY
SCIENCE
CHEMISTRY DIVISION
MICROBIOLOGY DIVISION
PATHOLOGY AND EPIDEMIOLOGY DIVISION
MATHEMATICS AND STATISTICS DIVISION
RESIDUE EVALUATION AND SURVEILLANCE DIVISION
FIELD SERVICE LABORATORIES DIVISION
FOOD INGREDIENT ASSESSMENT DIVISION
COMMODITY SERVICES
FOOD QUALITY ASSURANCE DIVISION
MEAT QUALITY DIVISION
FRUIT AND VEGETABLE QUALITY DIVISION
POULTRY AND DAIRY QUALITY DIVISION
ADMINISTRATIVE MANAGEMENT
BUDGET, PLANNING, AND EVALUATION DIVISION
PERSONNEL DIVISION
MANAGEMENT IMPROVEMENT DIVISION
FINANCE DIVISION
ADMINISTRATIVE SERVICES DIVISION
EXECUTIVE SECRETARIAT
COMPLIANCE
EVALUATION AND ENFORCEMENT DIVISION
PLANNING AND ANALYSIS DIVISION
REGULATIONS COORDINATION DIVISION
MEAT AND POULTRY STANDARDS AND LABELING DIVISION
MEAT AND POULTRY INSPECTION
TECHNICAL SERVICES
FIELD OPERATIONS
REGIONAL OFFICES

*NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# ORGANIZATION*

## OFFICE OF THE ADMINISTRATOR

- Maintains management control over the following activities delegated to FSQS by the Secretary of Agriculture:

  Inspection and grading programs for dairy products, fruits and vegetables, meat and poultry, and other foods;
  Inspection of the quality of egg products and regulation of the disposition of eggs containing harmful bacteria;
  Processing and distribution of various food products; and
  Transportation and sale of foods determined unsafe.

- Administers a Government-wide program to ensure the quality of food obtained by Federal agencies.

## SCIENCE PROGRAM (SCI)

- Works in conjunction with the Office of the Administrator to formulate FSQS scientific and laboratory policies and to coordinate research projects.

- Operates the FSQS regulatory field service laboratories and maintains liaison with other laboratories around the world.

- Conducts a program of scientific data collection and review.

- Conducts the food-borne hazard reporting system for the detection of human diseases stemming from bacteria in foods and the regulation of direct and indirect additives in meat and poultry.

### Chemistry Division (SCI)

- Develops analytical methods and approves those that are suitable for supporting a regulatory program.

- Conducts special studies for FSQS where necessary and performs comparison studies with Federal and commercial laboratories.

- Maintains a quality assurance program to ensure the validity of experimental results.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

Microbiology Division (SCI)

- Conducts a general microbiology program to identify pathogens and toxins in support of MPI field programs.
- Analyzes canned foods and determines the presence of extraneous material in food products in support of MPI field programs.
- Develops new methods for detecting antibiotic residues.
- Maintains a quality assurance program to ensure the validity of results.

Pathology and Epidemiology Division (SCI)

- Assists MPI with the development of criteria used in ante mortem and post mortem inspections of livestock and poultry.
- Operates a national diagnostic pathology program and a food-borne hazard reporting center to investigate potential risks of unsafe meats to human health.
- Studies the application of field tests in pathology and parasitology.

Residue, Evaluation, and Surveillance Division (SCI)

- Conducts monitoring and surveillance programs to determine the extent of drug, pesticide, antibiotic, and environmental residues in food of animal origin.
- Assists in the evaluation of cooperative residue programs performed by industry.
- Conducts toxicological studies of substances found in food.

Food Ingredient Assessment Division (SCI)

- Coordinates the establishment of FSQS nutritional policies and recommends research.
- Approves use of food additives in meat and poultry products.
- Determines safety of compounds and packages used by industry.

Field Service Laboratories Division (SCI)

- Performs chemistry, microbiology, and pathology studies in analyzing food and nutrition products.
- Supervises State laboratories under contract to FSQS to analyze food for chemical economic adulteration analysis.

COMPLIANCE PROGRAM (CP)

- Supervises FSQS monitoring and enforcement programs.
- Works with other FSQS branches to formulate new policies and programs.
- Coordinates the development of FSQS regulations and takes action to ensure regulatory compliance.
- Administers enforcement activities, advises the Administrator on matters of regulatory compliance, and maintains liaison with other enforcement groups.
- Develops the agency's labeling policy and standards for meat and poultry.
- Initiates actions to withdraw services and conduct debarment proceedings.

Regulations and Coordination Division (CP)

- Publishes FSQS regulations, instructions, and notices.
- Reviews regulations for adequacy, clarity, and compliance with agency requirements.

MEAT AND POULTRY INSPECTION (MPI)

- Ensures the wholesome quality of meat and poultry products in interstate and foreign commerce by in-plant inspection of all livestock and poultry as well as the reinspection of processed meat and poultry products.
- Conducts field tests and inspections of livestock, poultry, and derived products.
- Controls and disposes of condemned and inedible foods.
- Monitors processing facilities, approves new construction of plants and equipment, develops sanitary requirements, and reviews the inspection systems of countries exporting food to the United States.
- Monitors and evaluates State meat and poultry inspection programs.

Technical Services (MPI)

- Analyzes agricultural practices and scientific advances for their effect on food safety and public health.
- Develops procedures for inspecting livestock, poultry, and their processed products and coordinates the establishment of regulatory criteria concerning the disposition of carcasses.

- Develops requirements for facilities, equipment, and sanitation and approves new construction and equipment for meat and poultry plants.

- Prepares environmental considerations for the Meat and Poultry Inspection Program.

Field Operations (MPI)

- Inspects meat and poultry products during processing.

- Checks the accuracy of label information and monitors plants, other facilities, and individuals for compliance with legal orders.

- Inspects meat and poultry entering or leaving the United States.

Regional Offices (MPI)

- Plans and coordinates Field Operations programs for inspection, control of condemned products, and a variety of other activities relating to facilities and processing.

- Reviews State inspection programs and coordinates activities between the States and the Federal Government.

- Grants and suspends inspection privileges under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL*

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Office of the Administrator | 202-447-7025 | 332-E |
| Science Program | 202-447-2326 | 402-A |
| Chemistry Division | 202-447-7623 | 403-A |
| Microbiology Division | 202-447-4212 | 602-A |
| Pathology and Epidemiology Division | 301-344-2640 | 101 318-C<br>Beltsville, MD |
| Residue Evaluation and Surveillance Division | 202-447-8096 | 404-A |
| Field Service Laboratories Division | 202-447-4198 | 404-A |

*FTS numbers are the same.

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Compliance Program | 202-447-8803 | 344-E |
| Regulations Coordination Division | 202-447-3317 | 2940-S |
| Meat and Poultry Inspection | 202-447-3473 | 341-E |
| Technical Services | 202-447-3521 | 4911-S |
| Field Operations | 202-447-3679 | 4869-S |
| Food Ingredient Assessment | 202-447-7680 | 2148-S |

REGIONAL AND FIELD OFFICES

| | | |
|---|---|---|
| Area Supervisor | Region I<br>Meat and Poultry Inspection Program<br>New Hampshire Area Office<br>Federal Building and<br>U.S. Post Office<br>Room 433<br>Concord, NH 03301 | 603-834-4747 |
| Area Supervisor | Region II<br>Meat and Poultry Inspection Program<br>26 Federal Plaza<br>Room 1737<br>New York, NY 10007 | 212-264-1390 |
| Regional Director | Region III<br>Meat and Poultry Inspection Program<br>1421 Cherry Street<br>Seventh Floor<br>Philadelphia, PA 19102 | 215-597-4219 |
| Regional Director | Region IV<br>Meat and Poultry Inspection Program<br>1718 Peachtree Street, NW.<br>Room 216<br>Atlanta, GA 30309 | 404-257-3911 |
| Main Station Supervisor | Region V<br>Meat Quality Division<br>4101 South Halsted Street<br>Room 217<br>Chicago, IL 60609 | 312-353-5751 |

| | | |
|---|---|---|
| Regional Director | Region VI<br>Meat and Poultry<br>Inspection Program<br>1100 Commerce Street<br>Room 5F41<br>Dallas, TX 75242 | 214-729-9116 |
| Fed-State Supervisor | Region VIII<br>Poultry and Dairy<br>Quality Division<br>c/o Colorado Department<br>of Agriculture<br>2331 West 31st Avenue<br>Room 113<br>Denver, CO 80211 | 303-839-2825 |
| Regional Director | Region IX<br>Meat and Poultry<br>Inspection Program<br>620 Central Avenue, Building 2C<br>Alameda, CA 94501 | 415-536-7402 |
| Area Supervisor | Region X<br>Washington Area Office<br>Meat and Poultry<br>Inspection Program<br>711 South Capital Way<br>Evergreen Plaza Building<br>5th Floor<br>P.O. Box 2167<br>Olympia, WA 98507 | 206-434-9497 |

# STATUTORY AUTHORITIES

## Federal Meat Inspection Act

### Public Law 90-201   21 U.S.C. § 601 et seq.

The Federal Meat Inspection Act is the result of a 1967 congressional revision (the Wholesome Meat Act of 1967) of the original Meat Inspection Act of 1907. The purposes of the Act are to provide safe and wholesome meat and meat products and to ensure uniform inspection, labeling, and packaging of meats.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 1(m) | Gives a detailed definition of the word "adulterated" by including any carcass, meat, or meat product that is found to include poisonous or deleterious substances, including pesticides, chemicals, additives, or colorings that are found unfit for human food. |
| sec. 1(m)(2)(c) | Prohibits the use of any food additive determined unsafe under the Food, Drug, and Cosmetic Act (sec. 409). |
| sec. 2 | Expresses the concern of Congress to assure that meat and meat products are wholesome, properly marked, labeled, and packaged. |
| sec. 3 | Requires the Secretary to provide rules and regulations for animal inspection, and segregation for diseased animals. |
| sec. 4 | Requires a post mortem inspection of all animals slaughtered to determine possible adulteration. |
| sec. 10 | Prohibits any person, firm, or corporation from selling adulterated or misbranded meat and meat products. Also, this section prohibits the handling of meat and meat products in a way that causes adulteration or misbranding. |
| sec. 20 | Requires importation of meat only from countries maintaining inspection systems equivalent to United States systems. The section also requires the reinspection of products at the port of entry. |

| | |
|---|---|
| sec. 402 | Requires the detention and destruction of adulterated products found moving in commerce. |
| sec. 409 | Requires that tolerances established for various substances be coordinated with those established by the Food and Drug Administration under FFDCA section 408. |

### Regulatory Options Available Under Statute

- Prescribe and implement terms and conditions for destruction
- Refuse to inspect and pass or clear
- Refuse to stamp, mark, tag, or label
- Notify the Governor of the State
- Refuse to provide or withdraw inspection service
- Detain
- Proceed against, seize, and condemn
- Determine fine or imprisonment or both
- Issue injunctions

## The Poultry Products Inspection Act

### Public Law 90-492 21 U.S.C. § 451 et seq.

The Poultry Products Inspection Act was first passed in 1957, then amended in 1962 and 1968. The Act provides for the uniform inspection of poultry and poultry products and for the regulation of poultry processing and distribution practices. The principal purpose of the Act is to ensure that poultry and poultry products are wholesome, properly marked, labeled, and packaged.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 4(g) | Gives a detailed definition of the term "adulterated." "Adulteration" applies to any poultry carcass or poultry product that is found to contain added poisonous or deleterious substances, including pesticides, chemicals, additives, or colorings that are found unfit for human food within the meanings of sections 408 and 409 of the FFDCA. |
| sec. 1(y) | Defines the terms "pesticide chemical," "color additive," and "raw agricultural commodity" as having the same meanings as in FFDCA. |
| sec. 6(a) | Requires an ante mortem inspection of all poultry suspected of adulteration at official establishments or facilities subject to inspection under this Act. |

| | |
|---|---|
| sec. 6(b) | Requires a post mortem inspection of all birds processed and a quarantine and segregation if the birds are found unsafe for human food. |
| sec. 6(c) | Requires the condemnation and destruction of all adulterated birds. |
| sec. 9(a)(4) | Prohibits the sale, transport, or offer for sale of any adulterated or misbranded poultry products. |
| sec. 14 | Regulates the conditions under which poultry products for human food will be stored or handled to prevent adulteration or misbranding. |
| sec. 17 | Prohibits the importation of slaughtered poultry or poultry products unless they are healthful, wholesome, fit for human food, and not adulterated. They must contain no dye, chemical, preservative, or ingredient unfit for human consumption. |

### Regulatory Options Available Under Statute

- Condemn and destroy
- Refuse to render, provide, or withdraw inspection service
- Quarantine, segregate, and reinspect
- Withhold use
- Determine fine or imprisonment or both
- Prescribe conditions for storage and handling
- Destroy and prescribe terms and conditions for destruction
- Detain
- Proceed against, seize, and condemn
- Issue injunctions

## The Federal Food, Drug, and Cosmetic Act

### Public Law 69 21 U.S.C. §§ 301-392

The purpose of FFDCA is to safeguard public health by prohibiting the introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded and to regulate additives and toxins in foods. FSQS is given statutory authority under three sections of the Act.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 408 | Authorizes the establishment of tolerances for pesticide chemical residues in food in order to protect public health. |

| | |
|---|---|
| sec. 409 | Deems a food additive unsafe unless it is proven safe. |
| sec. 512 | Following the Drug Animal Amendments of 1968, a separate class of substances known as "new animal drugs" was established with FFDCA. Such substances are regulated when residues in foods exceed the tolerance levels established under this section. |

## Regulatory Options Available Under Statute

- Ban
- Set tolerances
- Deem products to be misbranded
- Establish standards or conditions
- Require registration or certification

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

Regulatory development at FSQS is a three-part process which begins with the placement of a regulatory initiative on the FSQS Work Plan. The initiative then follows through the Decision Log Movement, the Impact Analysis Movement, and the Docket Clock. (This is explained in greater detail in the steps below, and the diagrams which follow.) Both the Office of Primary Interest and the Regulations Coordination Division play a central role in this process. Also, the Meat and Poultry Inspection and Residue Monitoring Programs provide special assistance and information regarding decisions to regulate or rule against harmful adulterants in meat and poultry products.

1. The Office of Primary Interest (which may include any Division Office within FSQS) begins the regulatory process by entering an initiative onto the FSQS Work Plan. Once on the Work Plan, the initiative may be published in the Federal Register. Placement on the Work Plan also triggers the Decision Log Movement within FSQS. (Diagram 1)

2. Reviews and studies are conducted on all available information. Special assistance and information may also be provided by the Meat and Poultry Inspection and Residue Monitoring Programs.

3. When the decision is found to be significant or not significant an Impact Analysis Movement is prepared. (Diagram 2)

4. The Office of Primary Interest prepares the rule or regulation (Docket) and submits it to the Regulations Coordination Division for movement through the final review process (Docket Clock). This process involves the Office of Primary Interest, the Deputy Administrators, and the General Counsel. Also at this time, the Docket is submitted to Policy Development and Program Planning for the development of a public participation plan as appropriate. (Diagram 3)

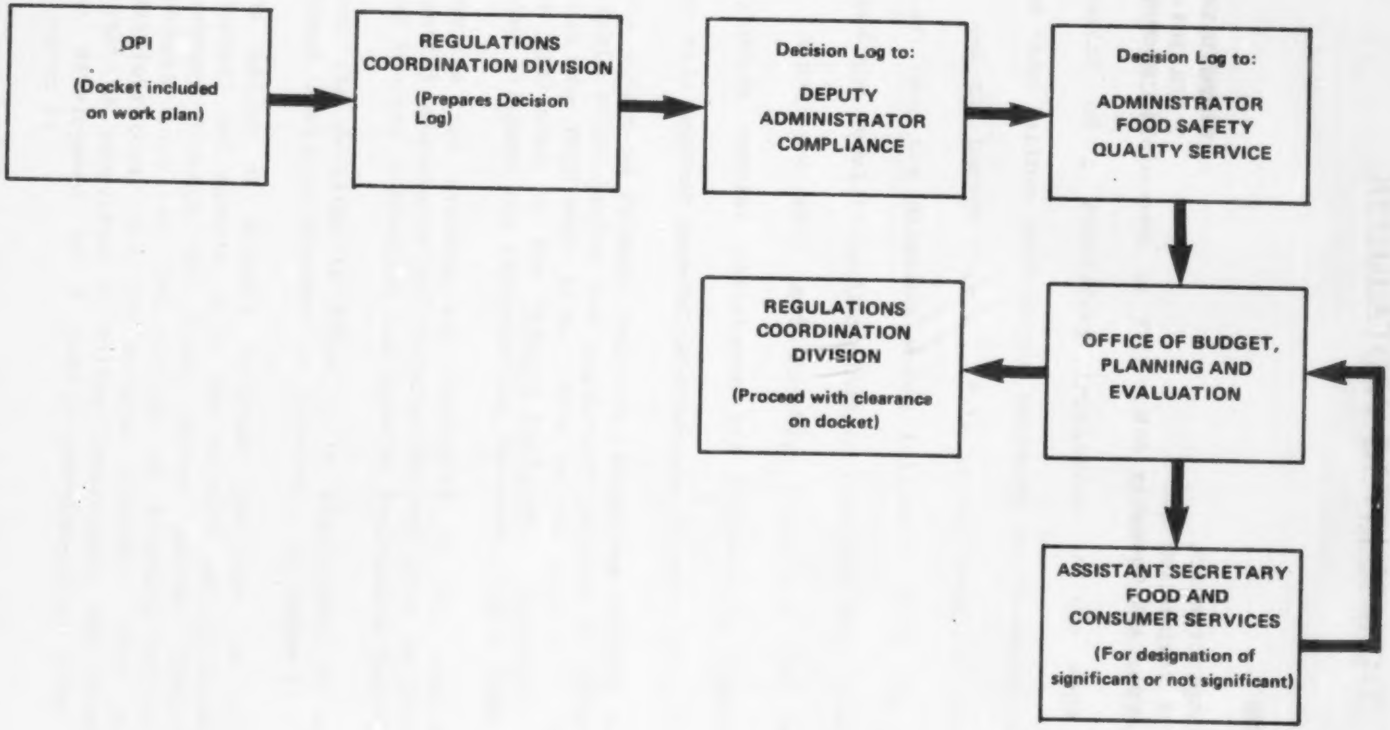
5. The approved Docket, along with a proposed public participation plan and comments, are presented to the Administrator for final approval.

6. The Proposed or Final Standard is published in the Federal Register.

EXISTING REGULATIONS

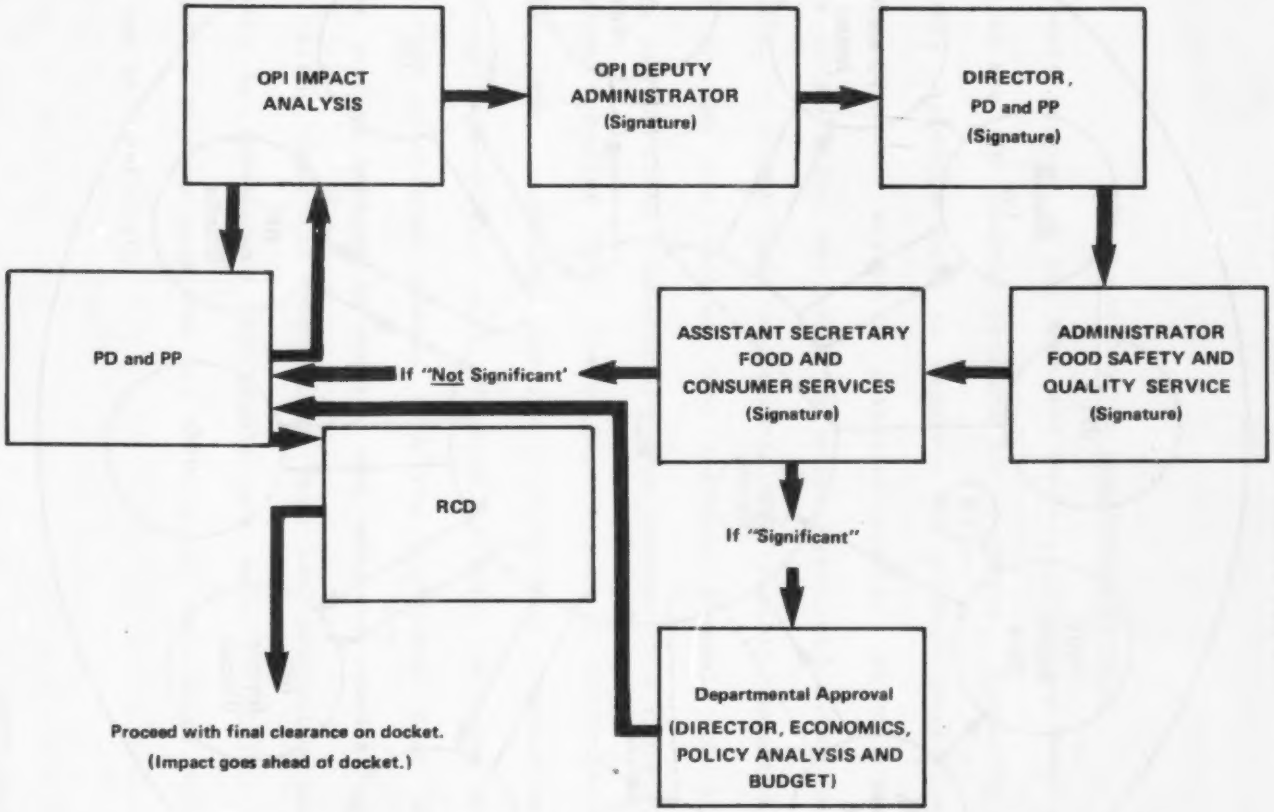
| | |
|---|---|
| Federal Meat Inspection Act | 9 CFR 301-335 |
| Poultry Products Inspection Act | 9 CFR 301-329, 381 |
| Federal Food, Drug, and Cosmetic Act | 21 CFR 1-1702 |

# Diagram 1. DECISION LOG MOVEMENT


OPI
(Docket included on work plan)
REGULATIONS COORDINATION DIVISION
(Prepares Decision Log)
Decision Log to:
DEPUTY ADMINISTRATOR COMPLIANCE
Decision Log to:
ADMINISTRATOR FOOD SAFETY QUALITY SERVICE
OFFICE OF BUDGET, PLANNING AND EVALUATION
REGULATIONS COORDINATION DIVISION
(Proceed with clearance on docket)
ASSISTANT SECRETARY FOOD AND CONSUMER SERVICES
(For designation of significant or not significant)

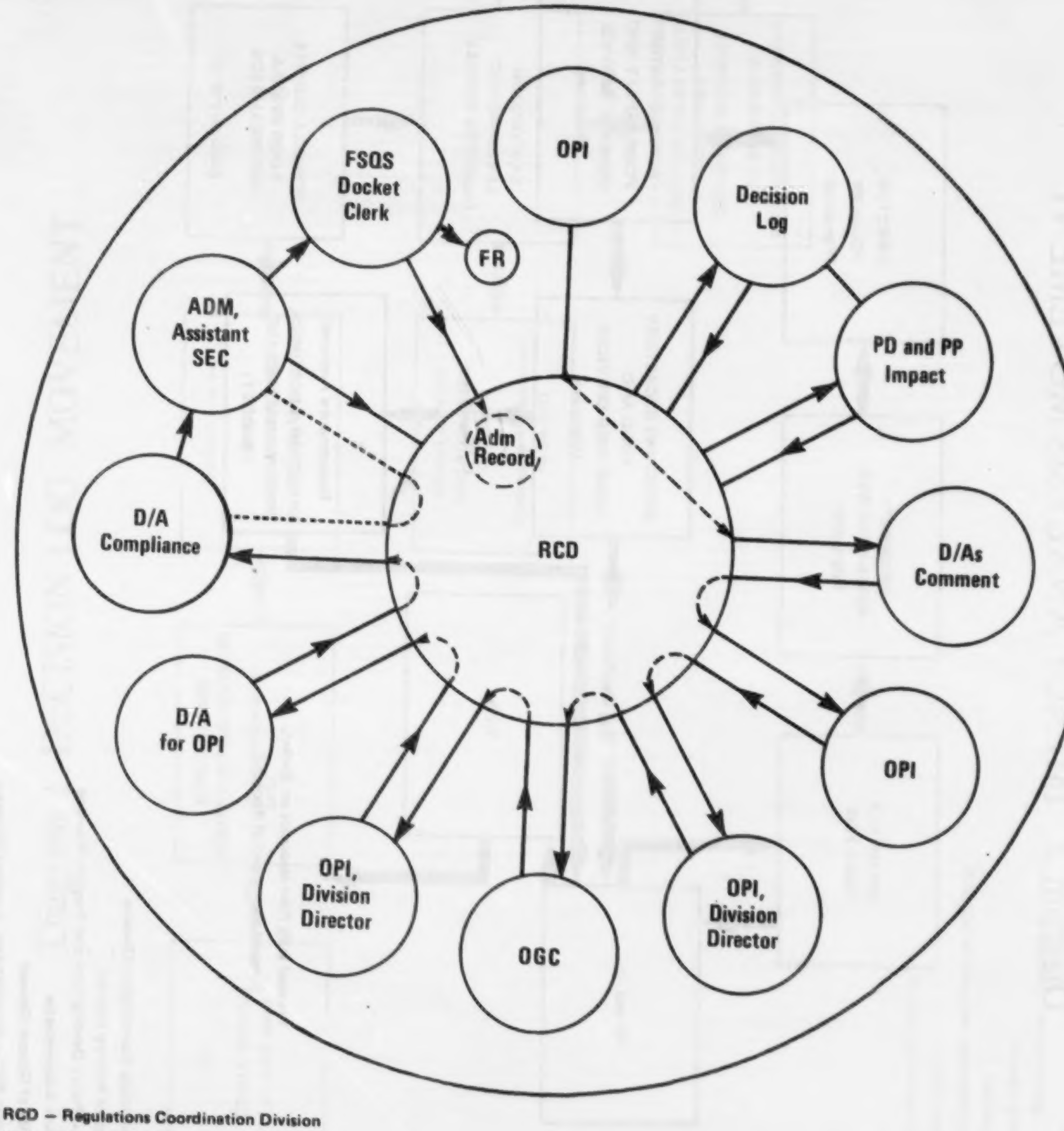
RCD – Regulations Coordination Division
OPI – Office of Primary Interest
PD and PP – Policy Development and Program Planning
D/A – Deputy Administrator
OGC – Office of General Counsel
ADM, Assistant SEC – Administrator, Assistant Secretary
FR – Federal Register

# Diagram 2. IMPACT ANALYSIS MOVEMENT


OPI IMPACT ANALYSIS
OPI DEPUTY ADMINISTRATOR (Signature)
DIRECTOR, PD and PP (Signature)
PD and PP
If "Not Significant'
ASSISTANT SECRETARY FOOD AND CONSUMER SERVICES (Signature)
ADMINISTRATOR FOOD SAFETY AND QUALITY SERVICE (Signature)
RCD
If "Significant"
Proceed with final clearance on docket.
(Impact goes ahead of docket.)
Departmental Approval (DIRECTOR, ECONOMICS, POLICY ANALYSIS AND BUDGET)

RCD – Regulations Coordination Division
OPI – Office of Primary Interest
PD and PP – Policy Development and Program Planning
D/A – Deputy Administrator
OGC – Office of General Counsel
ADM, Assistant SEC – Administrator, Assistant Secretary
FR – Federal Register

Diagram 3. DOCKET CLOCK


OPI
FSQS Docket Clerk
FR
Decision Log
ADM, Assistant SEC
PD and PP Impact
Adm Record
D/A Compliance
RCD
D/As Comment
D/A for OPI
OPI
OPI, Division Director
OGC
OPI, Division Director

RCD – Regulations Coordination Division
OPI – Office of Primary Interest
PD and PP – Policy Development and Program Planning
D/A – Deputy Administrator
OGC – Office of General Counsel
ADM, Assistant SEC – Administrator, Assistant Secretary
FR – Federal Register

# TOXICS-RELATED ACTIVITIES*

## Meat and Poultry Inspection Program

The basic purpose of the Meat and Poultry Inspection Program (MPI) is to assure safe meat and poultry products for consumers. Authority under the meat and poultry inspection acts to regulate and perform inspections begins when livestock or poultry arrive at slaughter plants. At this time, inspectors evaluate animals for exposure to drugs, pesticides, or other chemical adulterants. Should such adulteration be visibly detected, it is then retained by MPI and removed from consumer channels to prevent further marketing of the food. Immediately upon receipt of a violative result, the MPI region notifies FDA, State Department of Agriculture, EPA (for pesticides), MPI inspectors, and the producer that a violation occurred and the followup actions that will be taken by MPI. Followup actions usually require that additional animals from the particular farm be retained at slaughter pending testing to confirm that adequate remedial action has been taken. Also, agencies regulating drug and pesticide usage have the opportunity to investigate why regulations were violated. The resulting investigation reports give FDA and EPA insight into where potential program changes may be beneficial.

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*Included here are those activities identified as toxics-related from the information provided by each agency or office at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions, as well as new additions, to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

## Meat and Poultry Residue Program (MPR)

The Federal Meat Inspection Act and the Poultry Products Inspection Act authorize the United States Department of Agriculture (Meat and Poultry Inspection Program) to inspect meat and poultry prepared for transportation or sale in interstate commerce. Routine ante mortem and post mortem inspection cannot usually detect the presence or absence of a chemical or drug residue unless clinical signs are present. This makes laboratory analysis of tissues vital in obtaining information for dissemination to the Federal and State Agencies in controlling potential adulterants of the meat and poultry supply.

The Meat and Poultry Inspection (MPI) Program has developed a system to determine the existence of toxic residue problems and provide an active exchange with other government agencies and producers. There is a twofold effort on the part of MPI to control residues. In the first part, the monitoring phase is designed to randomly select and analyze edible tissues from animals and poultry for residues. This provides the needed information for incidences, trends, and compliance with tolerances. It has a 95 percent probability of detecting a residue when 1 percent or more of the animals or poultry going to slaughter contain detectable levels. It is not designed to detect and condemn violative product. However, the program identifies and reflects on production practices that utilize drugs and chemicals for the much-needed meat supply.

Marketing practices before and after slaughter emphasize why monitoring programs cannot do more. Marketing would be a catastrophy if all product was held until analyses were completed for all possible residues. Least of all, the need for holding facilities to prevent loss of product in itself would eliminate a "fresh" product from the market.

The time required for collecting, shipping, and analyzing tissues is not complementary to the speed of kill and movement of fresh product to market. However, it does permit a followup action on any further product identified from the same origin.

This leads to the surveillance phase, which consists of analysis plus control when a particular residue, if present, would make the meat unfit for food. All the followup sampling falls in this category whenever the monitoring program finds a residue violation or information is obtained that a residue problem may exist. This phase is always biased by knowledge of a specific problem and designed to answer specific questions. The various approaches used in this phase are:

1. Single Premise Residue Confirmation Program--
   testing of animals from a premise which was found to contain residues near or above violative levels on previous laboratory analyses.

2. Integrated Production Systems Residue Program--
   to determine whether a residue violation involves single premise or the entire operation under an integrated management system.

3. Inspector Initiated Samples--
   tissues analyzed for cause; suspicion of violative residues.

4. Investigation of Residue "Breaks"--
   to establish the existence of a break and formulate the necessary controls.

5. "Named" Residue Surveillance--
   to develop residue data on a compound in one or more species, evaluate a change in practice and determine that the National Residue Monitoring is representative of a smaller geographic area.

6. Method Development Residue Program--
   to collect samples for the final development of an analytical method.

As indicated by the descriptive titles, these programs are designed to answer specific questions and are terminated as soon as the answer is obtained.

Most often it is at the producers' facilities where--by accident or lack of concern--drugs and chemicals are misused. The law does not permit jurisdiction on their facilities, only at the slaughter plant. However, authority on the farm is governed by other Federal and State agencies.

# *DEPARTMENT OF HEALTH AND HUMAN SERVICES*

200 Independence Ave SW.
Washington, D.C. 20201

Locator: 202-245-6296
Information: 202-245-6343

On Sunday, May 4, 1980, the Department of Health and Human Services (DHHS) came into being as a result of the separation of the Department of Education from the 27-year-old Department of Health, Education, and Welfare. The new department was created by the Department of Education Organization Act, signed by President Carter on October 17, 1979, which provided for establishment of a separate Department of Education.

DHHS has a proposed fiscal 1981 budget of some $226 billion and is responsible for almost 300 programs conducted by 140,000 full-time employees working throughout the United States and the world. DHHS is the Federal Government's principal agency for furthering the good health of Americans and providing them with essential human services.

The new Department has four principle components:

- The Public Health Service conducts research, combats illness and disease, ensures safety of food and drugs, and supports and develops health care resources.

- The Health Care Financing Administration assists Americans in obtaining health care.

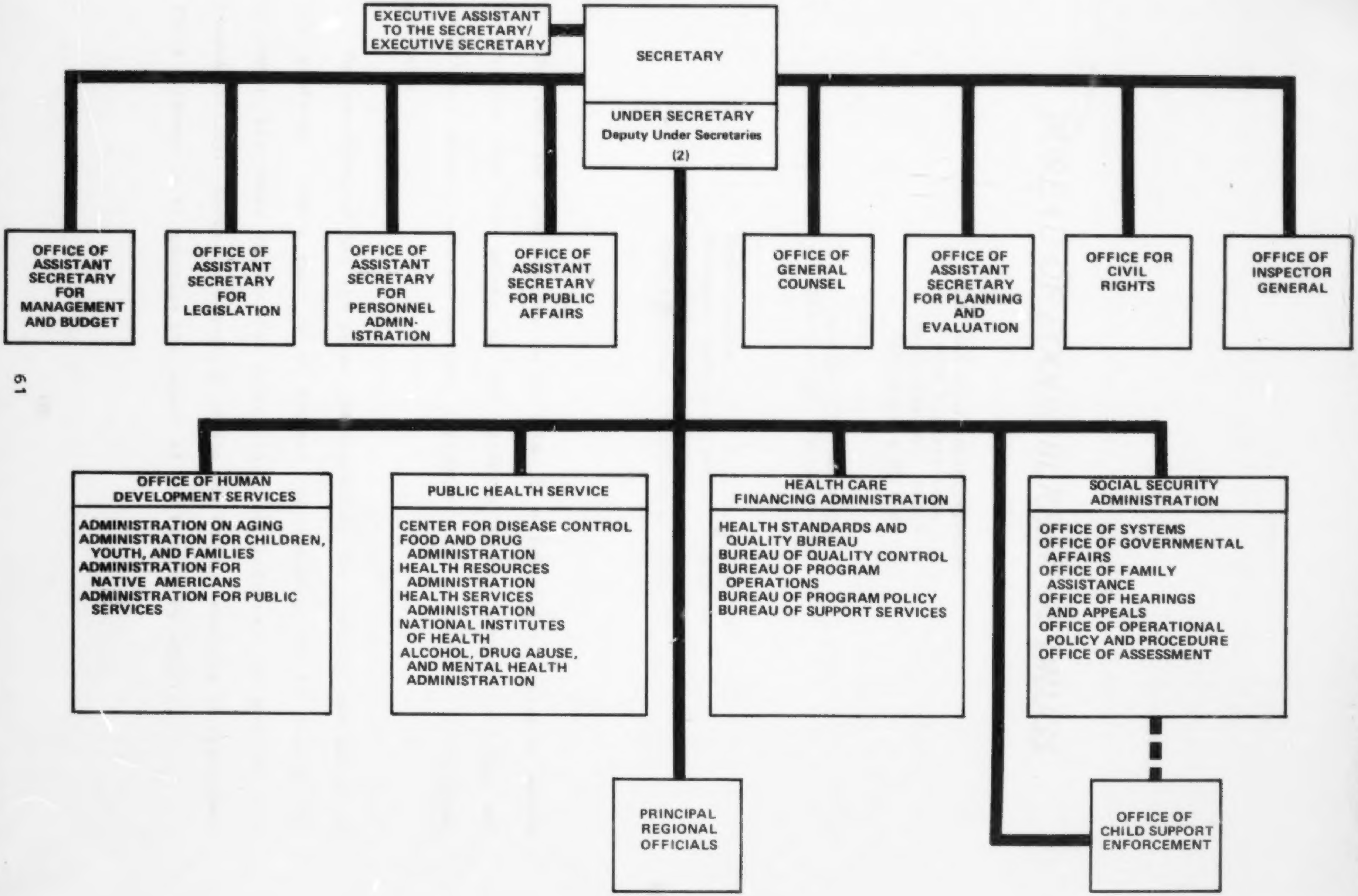
- The Office of Human Development Services provides social services to millions of needy Americans through Federal/State programs.

- The Social Security Administration administers the Social Security program, the Supplemental Security Income program, and the Aid to Families of Dependent Children program.

In addition to the activities of these four major components, DHHS administers a refugee assistance program authorized by the Refugee Assistance Act of 1980.

This publication highlights several agencies within DHHS. These include the Bureau of Food/the Bureau of Drugs and the National Center for Toxicological Research located within the Food and Drug Administration; the National Cancer Institute and the National Institute of Environmental Health Sciences of the National Institutes of Health; and the National Institute for Occupational Safety and Health.

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
## ORGANIZATIONAL CHART


EXECUTIVE ASSISTANT TO THE SECRETARY/ EXECUTIVE SECRETARY
SECRETARY
UNDER SECRETARY
Deputy Under Secretaries (2)
OFFICE OF ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
OFFICE OF ASSISTANT SECRETARY FOR LEGISLATION
OFFICE OF ASSISTANT SECRETARY FOR PERSONNEL ADMINISTRATION
OFFICE OF ASSISTANT SECRETARY FOR PUBLIC AFFAIRS
OFFICE OF GENERAL COUNSEL
OFFICE OF ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE FOR CIVIL RIGHTS
OFFICE OF INSPECTOR GENERAL
OFFICE OF HUMAN DEVELOPMENT SERVICES
ADMINISTRATION ON AGING
ADMINISTRATION FOR CHILDREN, YOUTH, AND FAMILIES
ADMINISTRATION FOR NATIVE AMERICANS
ADMINISTRATION FOR PUBLIC SERVICES
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
FOOD AND DRUG ADMINISTRATION
HEALTH RESOURCES ADMINISTRATION
HEALTH SERVICES ADMINISTRATION
NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
HEALTH CARE FINANCING ADMINISTRATION
HEALTH STANDARDS AND QUALITY BUREAU
BUREAU OF QUALITY CONTROL
BUREAU OF PROGRAM OPERATIONS
BUREAU OF PROGRAM POLICY
BUREAU OF SUPPORT SERVICES
SOCIAL SECURITY ADMINISTRATION
OFFICE OF SYSTEMS
OFFICE OF GOVERNMENTAL AFFAIRS
OFFICE OF FAMILY ASSISTANCE
OFFICE OF HEARINGS AND APPEALS
OFFICE OF OPERATIONAL POLICY AND PROCEDURE
OFFICE OF ASSESSMENT
PRINCIPAL REGIONAL OFFICIALS
OFFICE OF CHILD SUPPORT ENFORCEMENT

# *BUREAU OF FOODS/BUREAU OF DRUGS*

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Secretary's Office

Locator: 301-443-1544
Information: 301-443-1544

Organization..................page 66
Statutory Authority(ies)......page 70
Regulatory Development........page 74
Toxics-Related Activities.....page 75

The Food and Drug Administration (FDA) is a scientific regulatory agency responsible for the safety of the Nation's foods, cosmetics, human and veterinary drugs, medical devices, biologics, and electronic radiological products.

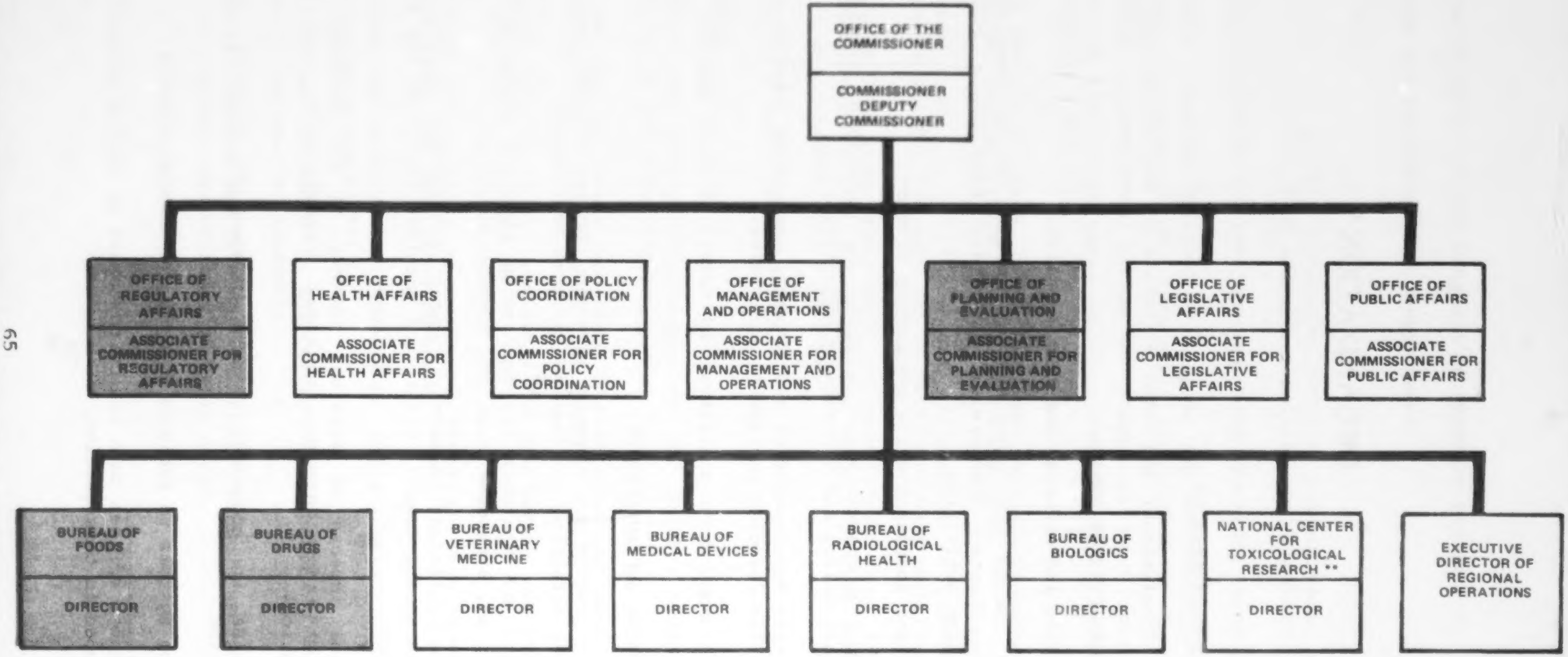
The manufacturer has the prime responsibility for ensuring the safety of its products. FDA's role is to monitor the industry and to provide the consumer the best assurances possible that industry is meeting its responsibility. Given the magnitude of the job and the scarcity of resources, FDA's strategy is to maximize the impact of its regulatory efforts.

This strategy is implemented by: (1) working with manufacturers to identify critical control points and develop good manufacturing practices; (2) statistically sampling establishments and products to identify problem areas and to measure the effectiveness of manufacturers' quality control efforts; and (3) conducting a safety review of all food and drug components to determine if they pose any hazard in light of ever new scientific evidence and techniques.

This section covers the activities of the Bureau of Foods and the Bureau of Drugs. The functions and responsibilites of the National Center for Toxicological Research are covered in a separate section.

# FOOD AND DRUG ADMINISTRATION

## ORGANIZATIONAL CHART*


OFFICE OF THE COMMISSIONER
COMMISSIONER DEPUTY COMMISSIONER
OFFICE OF REGULATORY AFFAIRS
ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS
OFFICE OF HEALTH AFFAIRS
ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS
OFFICE OF POLICY COORDINATION
ASSOCIATE COMMISSIONER FOR POLICY COORDINATION
OFFICE OF MANAGEMENT AND OPERATIONS
ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS
OFFICE OF PLANNING AND EVALUATION
ASSOCIATE COMMISSIONER FOR PLANNING AND EVALUATION
OFFICE OF LEGISLATIVE AFFAIRS
ASSOCIATE COMMISSIONER FOR LEGISLATIVE AFFAIRS
OFFICE OF PUBLIC AFFAIRS
ASSOCIATE COMMISSIONER FOR PUBLIC AFFAIRS
BUREAU OF FOODS
DIRECTOR
BUREAU OF DRUGS
DIRECTOR
BUREAU OF VETERINARY MEDICINE
DIRECTOR
BUREAU OF MEDICAL DEVICES
DIRECTOR
BUREAU OF RADIOLOGICAL HEALTH
DIRECTOR
BUREAU OF BIOLOGICS
DIRECTOR
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH **
DIRECTOR
EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS

*NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

**NOTE: Although NCTR falls under the organizational structure of FDA, the Center's operating authority is derived from an Interagency agreement between DHHS and EPA. Because of the complexity of its organizational ties and the extent of its toxics-related activities, NCTR is developed separately in this Overview.

# ORGANIZATION*

## OFFICE OF REGULATORY AFFAIRS

- Assists Commissioner and other officials on regulations and compliance issues that have an impact on policy development, execution, and long-range program goals.
- Establishes and enforces compliance policy.
- Acts as liaison with other Federal agencies on FDA compliance matters and coordinates Agencywide voluntary compliance and industry information activities.
- Directs and coordinates FDA regulatory process.
- Evaluates proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.
- Coordinates development of new or novel Agencywide compliance programs, such as bio-research monitoring activities.
- Monitors compliance activities to ensure uniform application of FDA policy.

## OFFICE OF PLANNING AND EVALUATION

- Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.
- Initiates and monitors the Agencywide planning system including the 5-year plan, strategic plan, and functional plans.
- Conducts operations research, economic and special studies as a basis for forecasting trends, needs, and problems requiring FDA solutions or involvement.
- Evaluates impacts of external factors on FDA programs, including industry and economics, consumer expectations, and protective legislation.
- Recommends new programs, changes in existent programs, and program priorities.
- Develops systems to evaluate FDA program accomplishments.

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*NOTE: Only those offices that deal with toxics or toxics-related issues are developed in this section.

- Evaluates impact of FDA programs on consumer protection.

- Manages the FDA Evaluation Review Board.

BUREAU OF FOODS

- Develops FDA policy involving safety, composition, quality, and labeling of foods, food additives, colors, and cosmetics.

- Conducts research and develops standards regarding these products.

- Conducts research designed to improve the detection, prevention, and control of contamination responsible for illness or injury from these products.

- Develops and promulgates good manufacturing practices for food processing industries.

- Plans FDA surveillance, compliance, and regulatory activities relating to foods, food additives, colors, and cosmetics.

- Reviews industry petitions and recommends regulations for food standards and for the safe use of color and food additives.

- Collects and interprets data on nutrition, food additives, and environmental factors affecting the total chemical result posed by direct and indirect food additives.

- Maintains a nutrition data bank.

BUREAU OF DRUGS

- Develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use.

- Reviews and evaluates new drug applications and notices of claimed investigational exemptions for new drugs.

- Develops and implements standards for the safety and effectiveness of all over-the-counter drugs.

- Monitors the quality of marketed drugs through product testing, surveillance and compliance programs.

- Develops and promulgates regulations and guidelines for current good manufacturing practices.

- Develops and disseminates information and educational materials about drugs to the medical community.

- Conducts research and develops scientific standards on the composition, quality, safety, and efficacy of human drugs.

- Collects and evaluates information on the effects and use trends of marketed drugs.
- Monitors prescription drug advertising and promotional labeling to ensure accuracy and integrity.
- Analyzes data on accidental poisonings and disseminates toxicity and treatment information on household products and medicines.
- Evaluates applications for methadone treatment centers and other activities using methadone or similar drugs.
- Directs the FDA antibiotic and insulin certification program.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Office of Regulatory Affairs | 301-443-1594 | HFC-1 |
| Office of Planning and Evaluation | 301-443-4230 | HFP-1 |
| Bureau of Foods | 202-245-1057 | HFF-1 |
| Bureau of Drugs | 301-443-2894 | HFD-1 |

REGIONAL AND FIELD OFFICES

| Division/Office | Phone | Mail Stops |
|---|---|---|
| Regional Food and Drug Director | 617-223-1278<br>FTS: 8-223-1278 | Region I<br>HFR-11<br>585 Commercial Street<br>Boston, MA 02109 |
| Regional Food and Drug Director | 212-965-5416<br>FTS: 8-663-5416 | Region II<br>HFR-21<br>830 3rd Avenue<br>Brooklyn, NY 11232 |
| Regional Food and Drug Director | 215-597-4390<br>FTS: 8-597-4390 | Region III<br>HFR-31<br>2nd and Chestnut Streets<br>Room 900<br>Philadelphia, PA 19106 |

*FTS numbers are the same.

| Division/Office | Phone | Mail Stops |
|---|---|---|
| Regional Food and Drug Director | 404-881-4266<br>FTS: 8-257-4266 | Region IV<br>HFR-41<br>880 West Peachtree Street, N.W.<br>Atlanta, GA 30309 |
| Regional Food and Drug Director | 312-353-1047<br>FTS: 8-353-1047 | Region V<br>HFR-51<br>175 West Jackson Boulevard<br>Room A-1945<br>Chicago, IL 60604 |
| Regional Food and Drug Director | 214-749-2735<br>FTS: 8-729-0317 | Region VI<br>HFR-61<br>3032 Bryan Street<br>Dallas, TX 75204 |
| Regional Food and Drug Director | 816-374-5646<br>FTS: 8-758-5646 | Region VII<br>HFR-71<br>1009 Cherry Street<br>Kansas City, MO 64106 |
| Regional Food and Drug Director | 303-837-4915<br>FTS: 8-327-4915 | Region VIII<br>HFR-81<br>U.S. Customhouse<br>721 19th Street<br>Room 500<br>Denver, CO 80202 |
| Regional Food and Drug Director | 415-556-2062<br>FTS: 8-556-2062 | Region IX<br>HFR-91<br>U.N. Plaza Federal Office Building<br>Room 526<br>San Francisco, CA 94102 |
| Regional Food and Drug Director | 206-442-5304<br>FTS: 8-399-5304 | Region X<br>HFR-01<br>909 1st Avenue<br>Room 5003<br>Seattle, WA 98174 |

# STATUTORY AUTHORITIES

## The Federal Food, Drug, and Cosmetic Act (FFDCA)

### Public Law 717 21 U.S.C. §§ 301-392

The Federal Food, Drug, and Cosmetic Act was passed in 1938 to expand the Food and Drugs Act of 1906. National legislation in this area became necessary as competition between food manufacturers for sales profits led to the debasement and/or the mislabeling of foods and other products. However, weaknesses in the 1906 Act were pointed out when 107 deaths resulted from "Elixir of Sulfanilamide." This incident called attention to the need for premarket approval of new drugs. The 1938 Act required predistribution clearance for safety of new drugs and brought cosmetics and devices under FDA regulation as well.

The purposes of the Food, Drug and Cosmetic Act are to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that medical devices are safe and effective for their intended uses; that drugs for human and animal use are not adulterated or misbranded and are safe and effective for their intended use, including drugs used in medicated feeds for animals; that cosmetics are safe and properly labeled; and that packaging and labeling of these products is truthful and informative.

Since 1938, the Act has been amended several times. Among the more prominent amendments have been the Food Additives Amendment of 1958, which prohibits the introduction of new food additives until the manufacturer can prove their safety; the Color Additive Amendments of 1960 which gave FDA authority to control the conditions for safe use of a color additive, including the amount of color used in a product; and the Drug Amendments of 1962, which required among other things that all drugs be proven effective as well as safe (only proof of safety was required under the 1938 statute). The 1962 Amendments also gave FDA authority to regulate prescription drug advertising. The responsibility for regulating the advertising of drugs sold over the counter is assigned to the Federal Trade Commission.

Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 301 | Details prohibitions under the Act. |
| sec. 302, 303, 304 | Injunctions, penalties, seizures. |
| sec. 401 | Authorizes FDA to promulgate regulations fixing definitions and standards of identity quality, and fill for foods. |
| sec. 402(a)(1) | A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health, or; |
| sec. 402(a)(2) | if it contains any added poisonous or deleterious substance. |
| sec. 403 | Details reasons for deeming foods misbranded. |
| sec. 406 | Authorizes FDA to set tolerances for poisonous or deleterious substances in food which cannot be avoided by good manufacturing practice. |
| sec. 409(a) | A food additive shall be deemed unsafe unless it is exempted from sec. 402(a) or its safe use is otherwise regulated. |
| sec. 409(b) | Allows public to petition FDA to regulate food additives. |
| sec. 409(c)(1) | Requires FDA to establish regulations detailing conditions for safe use of particular food additives, or deny sec. 409(b) petitions. |
| sec. 409(c)(3) | No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. |
| sec. 409(c)(5) | Other relevant factors such as probable quantity of consumption of additive, cumulative effects and safety factors shall be considered. |
| sec. 409(d) | Empowers FDA to take initiative at any time to propose regulations prescribing conditions of safe use of food additives. |

| | |
|---|---|
| sec. 501 | Details reasons for deeming drugs and devices to be adulterated. |
| sec. 502 | Details reasons for deeming drugs and devices to be misbranded. |
| sec. 503(a) | Allows FDA to exempt certain drugs and devices from labeling and packaging requirements. |
| sec. 503(b) | Describes types of drugs that shall be dispensed by prescription only, and requirements for labeling a prescription. |
| sec. 505 | Requires manufacturers to submit new drug applications to FDA for approval prior to introducing a new drug into interstate commerce. |
| sec. 505(e) | Allows the Secretary, DHHS to suspend a new drug application immediately if the substance presents an imminent hazard to health. |
| sec. 505(i) | Authorizes FDA to establish regulations permitting the shipment of investigational new drugs in interstate commerce without an approved new drug application. |
| sec. 510 | Requires registration and listing by manufacturers of drugs and devices. |
| sec. 513 | Establishes a classification system for devices. |
| sec. 514 | Establishes rulemaking procedures for issuing device performance standards. |
| sec. 515 | Requires premarket approval requirements for Class III devices. Requires that benefit to the public be shown. |
| | Allows FDA to ban unsafe or ineffective devices. |
| sec. 516 | Allows FDA to ban devices that present substantial deception or unreasonable and substantial risk of illness or injury. |
| sec. 701 | Authorizes FDA to issue regulations for the efficient enforcement of the Act. |
| sec. 702 | Authorizes FDA to conduct examinations and inspections, to execute and serve search warrants, to seize products, and make arrests. |
| sec. 703 | Requires carriers and recipients of foods, drugs, devices, or cosmetics in interstate commerce to allow FDA access to their records. |
| sec. 704 | Allows FDA to conduct inspections. |

| | |
|---|---|
| sec. 706 | Details requirements for listing and certification of color additives for foods, drugs, and cosmetics. |
| sec. 706(b) 5(B) | A color additive shall be deemed unsafe and shall not be listed if it induces cancer when ingested by man or animal. |

## Regulatory Options Available Under Statute

- Ban
- Set tolerances
- Deem products to be misbranded
- Establish standards or conditions
- Require registration or certification
- Require premarket approval
- Publicize
- Injunction
- Seizure
- Conduct hearings
- Subpoena
- Recall
- Issue or change regulation
- Inspect
- Sample and test
- Administrative detention
- Labeling review
- Adverse findings letter

# REGULATORY DEVELOPMENT

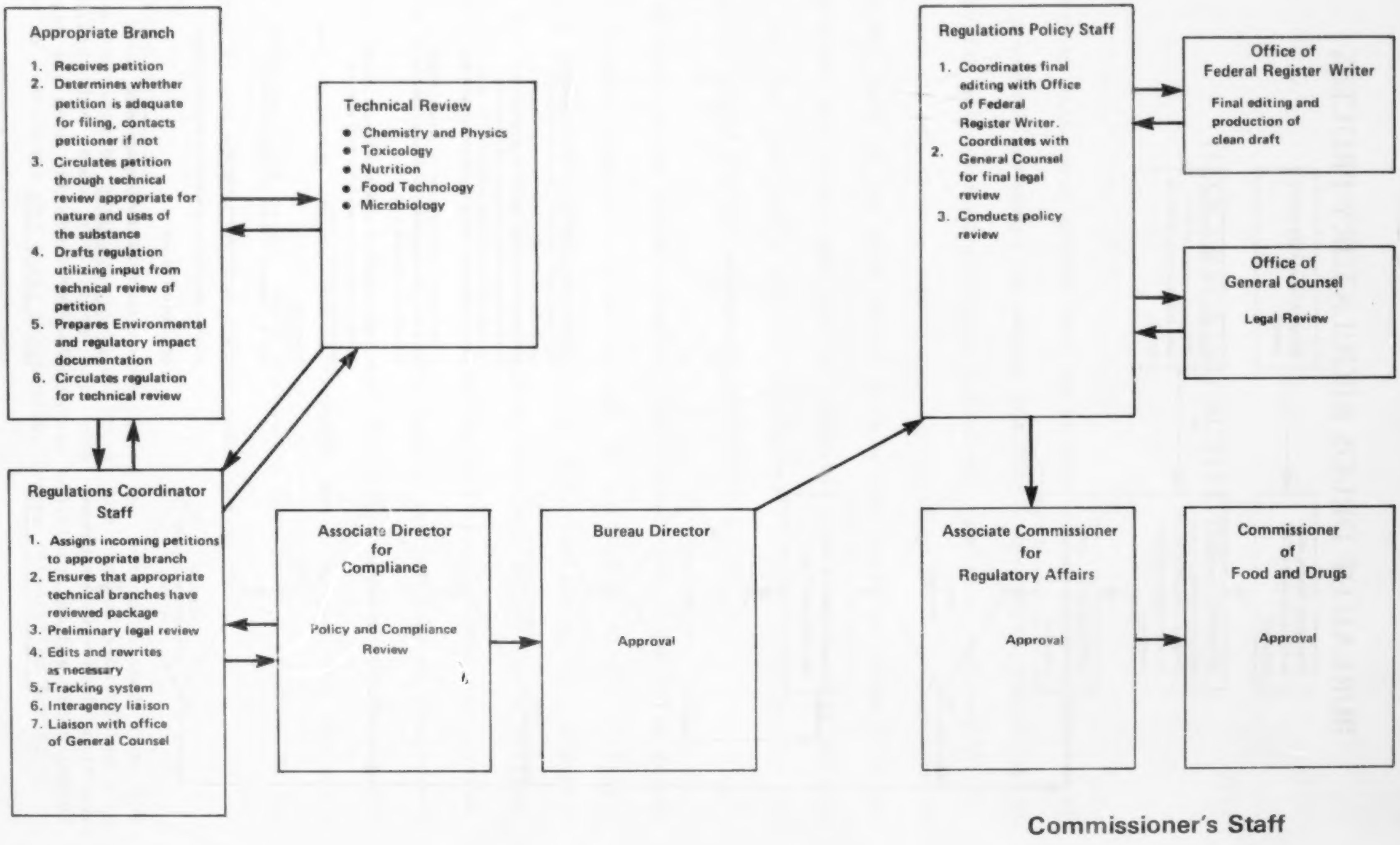
## REGULATORY PROCESS

The following flowcharts highlight the regulatory processes followed by the Bureau of Foods and the Bureau of Drugs. Although the step-by-step approach to regulatory development differs within the individual Bureaus, the most important regulatory proposals generated by either Bureau must be submitted to the Commissioner's Staff Offices for final approval. (Execution of some routine, repetitive regulatory procedures is delegated by the Commissioner to FDA Bureau Directors.) The regulatory process within the Commissioner's Staff follows the same path, regardless of which Bureau submits the regulatory proposal.

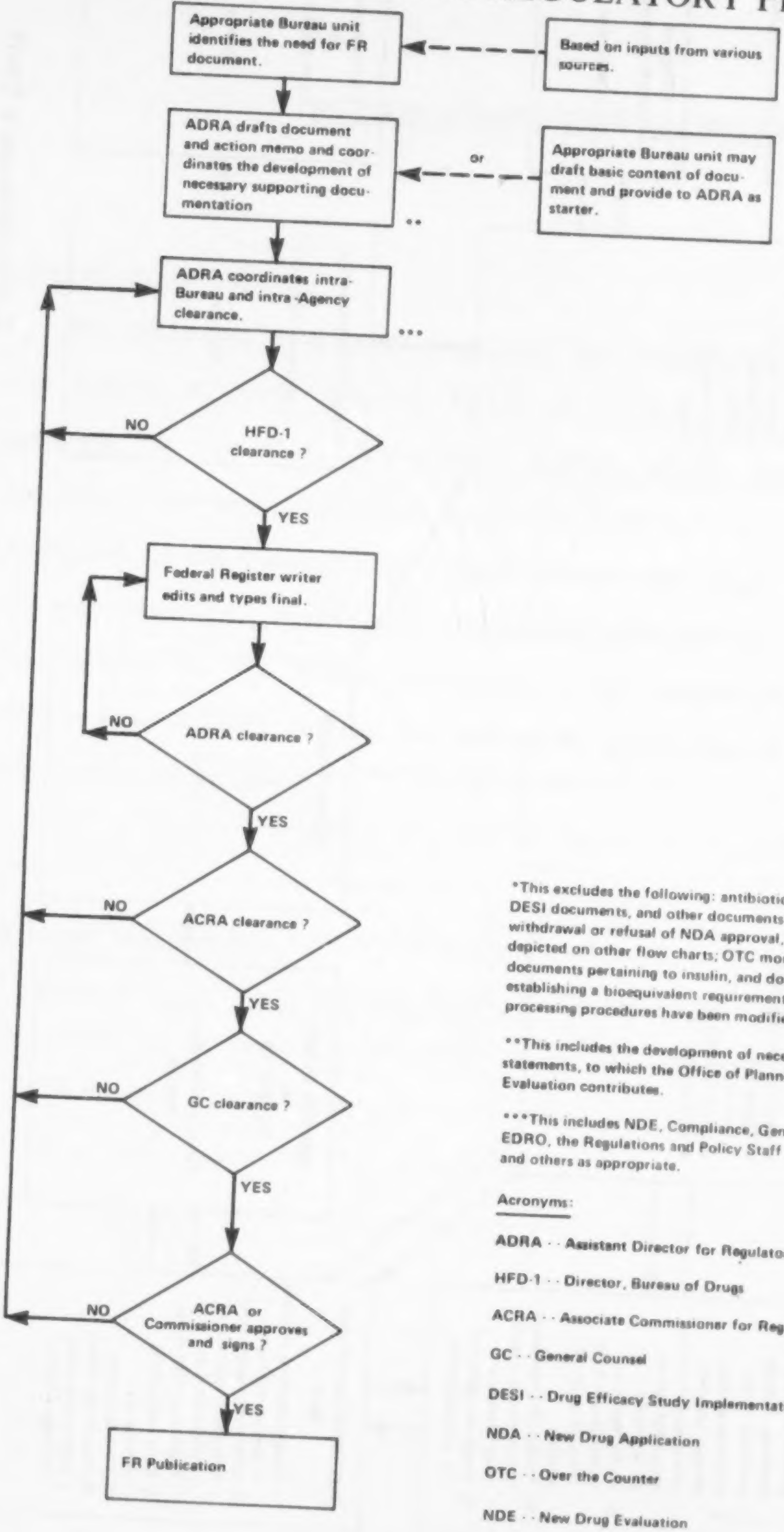
## EXISTING REGULATIONS

| | |
|---|---|
| Federal Food, Drug, and Cosmetic Act | 21 CFR 1-1299 |

# BUREAU OF FOODS REGULATORY PROCESS


Appropriate Branch
1. Receives petition
2. Determines whether petition is adequate for filing, contacts petitioner if not
3. Circulates petition through technical review appropriate for nature and uses of the substance
4. Drafts regulation utilizing input from technical review of petition
5. Prepares Environmental and regulatory impact documentation
6. Circulates regulation for technical review
Technical Review
• Chemistry and Physics
• Toxicology
• Nutrition
• Food Technology
• Microbiology
Regulations Coordinator Staff
1. Assigns incoming petitions to appropriate branch
2. Ensures that appropriate technical branches have reviewed package
3. Preliminary legal review
4. Edits and rewrites as necessary
5. Tracking system
6. Interagency liaison
7. Liaison with office of General Counsel
Associate Director for Compliance
Policy and Compliance Review
Bureau Director
Approval
Regulations Policy Staff
1. Coordinates final editing with Office of Federal Register Writer.
2. Coordinates with General Counsel for final legal review
3. Conducts policy review
Office of Federal Register Writer
Final editing and production of clean draft
Office of General Counsel
Legal Review
Associate Commissioner for Regulatory Affairs
Approval
Commissioner of Food and Drugs
Approval
Commissioner's Staff

# BUREAU OF DRUGS REGULATORY PROCESS


Appropriate Bureau unit identifies the need for FR document.
Based on inputs from various sources.
ADRA drafts document and action memo and coordinates the development of necessary supporting documentation
or
Appropriate Bureau unit may draft basic content of document and provide to ADRA as starter.
**
ADRA coordinates intra-Bureau and intra-Agency clearance.
***
NO
HFD-1 clearance ?
YES
Federal Register writer edits and types final.
NO
ADRA clearance ?
YES
NO
ACRA clearance ?
YES
NO
GC clearance ?
YES
NO
ACRA or Commissioner approves and signs ?
YES
FR Publication

*This excludes the following: antibiotic documents, DESI documents, and other documents relating to withdrawal or refusal of NDA approval, which are depicted on other flow charts; OTC monographs, . . . documents pertaining to insulin, and documents establishing a bioequivalent requirement for which processing procedures have been modified somewhat.

**This includes the development of necessary impact statements, to which the Office of Planning and Evaluation contributes.

***This includes NDE, Compliance, General Counsel, EDRO, the Regulations and Policy Staff of ACRA, and others as appropriate.

Acronyms:

ADRA - - Assistant Director for Regulatory Affairs

HFD-1 - - Director, Bureau of Drugs

ACRA - - Associate Commissioner for Regulatory Affairs

GC - - General Counsel

DESI - - Drug Efficacy Study Implementation

NDA - - New Drug Application

OTC - - Over the Counter

NDE - - New Drug Evaluation

EDRO -- Executive Director of Regional Operations

# TOXICS-RELATED ACTIVITIES*

The Program Management System (PMS) is an Agencywide system consisting of the vital processes necessary to manage the FDA. It can be viewed as an umbrella system encompassing planning, budgeting, reporting, and evaluation. The PMS covers all FDA program activities. Integral to PMS is a framework of nine programs, such as the Food Safety Program and the Human Drugs Program. These 9 programs are subdivided into 41 projects; for example, Drug Quality Assurance and Food Sanitation and Quality Control. These projects are the basic building blocks for all management activities.

Keeping track of the accomplishments, performance, and impact of an agency with such diverse responsibilities as FDA is difficult, albeit critical. Because much authority and responsibility is decentralized in FDA, a system using the PMS structure has been developed to regularly assess the objectives, the tactics, and the accomplishments of Agency activities. Under this system, each of the Agency's PMS projects is periodically evaluated by an independent team headed by the Office of Planning and Evaluation. These PMS evaluations focus on key project issues and strategies which assess the project's direction, problems, and needs. Each evaluation results in a briefing to the Commissioner by the manager of the project under evaluation.

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*Included here are those activities identified as toxics-related from the information provided by each agency or office at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions, as well as new additions, to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration Staff.

The following descriptions highlight projects that typify toxics-related activities by FDA.

## Chemical Contaminants

This project consists of identifying and assessing the health risks posed by chemical contaminants through surveillance, research, and regulatory initiatives. Toxic metals, pesticides, and industrial chemicals are monitored, as well as imported foods and foods grown near nuclear power plants. There is ongoing work to establish policies for the use of sewage sludge and effluents on food, forage, and feed crops.

## Food Additives

This project evaluates petitions submitted by manufacturers of additives, monitors the use of additives in processed foods, reviews the safety of the GRAS (Generally Recognized As Safe) list and other food additive substances, and provides scientific support to regulatory responsibilities under the Food Safety program. In addition, the Food Additive Project is part of the FDA's bio-research monitoring activities which include Good Laboratory Practices (GLP) inspections of testing facilities, toxicity studies on food and color additives and GRAS substances, and the cyclic review of food ingredients.

## Mycotoxins and Other Natural Poisons

This project's mission is to identify mold toxins (mycotoxins) which can contaminate food, and those food plant metabolites which can be toxic, and to establish the means whereby such toxins in foods can be controlled. The Agency seeks to encourage self-regulation by educating the affected industries on the technical aspects of this problem. It develops information on the conditions necessary to prevent contamination from these toxins. The project also interacts with the USDA and the Natural Poisons project to provide support for developing analytical methods and other control procedures which enable industry to screen out toxin-contaminated products from the food supply.

## Nutrition

New initiatives are being taken in the area of nutrient toxicity and interactions. These deal with the toxicity of essential nutrients which are ingested at levels significantly higher than the human requirement, as well as the changes in requirements modified by the interactions of these essential nutrients with other nutrients, food additives, dietary supplements and environmental contaminants. The Nutrition project conducts surveillance programs designed to evaluate new and traditional products for nutritional composition, maintains the Food Composition Data Bank to provide necessary background data to develop new guidelines and standards, and conducts research in nutrient toxicity and nutrient interactions. Where false or misleading nutritional claims are made on or for a food product, action is taken under the Food Economics Program.

## Shellfish Safety

Shellfish, such as oysters, clams, and mussels, become contaminated from polluted waters because of their ability to concentrate pathogenic microorganisms and toxic chemicals from their environments. This project develops guidelines and regulations promoting sanitation in the control of growing waters, harvesting procedures, processing facilities, and marketing practices. Also, as part of the National Shellfish Sanitation Program (NSSP), a cooperative State/Federal Program, this project develops enforceable standards of quality for shellfish products.

## Cosmetics

The mission of this project is to ensure that cosmetic products are safe, truthfully and informatively labeled, and truthfully packaged. The major project activities are: conducting research to determine cosmetics' safety and identify hazardous ingredients; maintaining registries for the voluntary filing of cosmetic manufacturers, and cosmetic formulations, and the reporting of adverse reactions to cosmetics; maintaining surveillance to ensure compliance with regulations; and supporting regulatory activities.

## Biopharmaceutics

FDA has established a Biopharmaceutics Project to address both the bioavailability and bioequivalence of drugs. The bioavailability of a drug refers to the amount of active drug substance which becomes systemically available to achieve its therapeutic action. If too much active drug substance were unexpectedly introduced systemically, it could lead to toxic or adverse reactions, whereas deficient levels could cause inadequate therapeutic response.

Under this project, FDA develops bioequivalence regulations, bioavailability guidelines, and reviews and evaluates pharmacokinetic protocols for possible labeling revision and studies for new chemical entities and dosage forms.

Also, the project interacts regularly with the activities of various other projects within the Human Drug Program, including New Drug Evaluation, Drug Quality Assurance, Prescription Drug Labeling, Antibiotic Insulin Certification, OTC Drug Evaluation and Bioresearch Monitoring.

## Drug Experience and Trend Analysis

The mission of this project is to monitor the short- and long-term effects and uses of marketed drugs to establish a scientific basis for regulatory actions, and support new drug review processes. It monitors drug experience reports submitted to FDA and drug monitoring studies through the application of epidemiological techniques. The project analyzes, maintains, and disseminates information regarding drug use trends and drug experience data to help reduce adverse effects. The information gathered by the Drug Experience and Trend Analysis project also helps to satisfy the information needs of other FDA projects, including New Drug Evaluation, Drug Abuse Treatment Monitoring and Poison Control. In addition, the project performs reviews of the Adverse Reaction Section of labels for the Prescription Drug Labeling project.

## Drug Quality Assurance

Congress has vested in FDA the responsibility to monitor the overall quality of drugs; maintain drug establishment registration and drug product listing; and take necessary measures to ensure that the manufacturing, processing, packing, and holding of drugs, and the facilities and controls used in these processes, are such that the highest quality products feasible may be marketed.

Marketed drugs have been found to be deficient in many ways, such as being subpotent or superpotent, contaminated with other drugs, compounded with the wrong active ingredient, and contaminated with microorganisms. As a result of such deficiencies, serious injuries and deaths have occurred. The project seeks to monitor the quality of all drugs marketed in the U.S. through inspections and sample analyses. To support this effort, the project conducts pharmaceutical research on methodology and standards in drug chemistry, drug bioanalysis, and drug microbiology; and participates in domestic and international compendial, and other methodology/standard-setting activities. In addition, it strives to achieve voluntary support from the pharmaceutical industry whenever possible by informing them of problems with either their product or their manufacturing process so that correction may be as expeditiously as possible.

Finally, the Drug Quality Insurance project develops and maintains a listing of all products subject to the provisions of the Drug Listing Act of 1972. It registers and maintains a current listing of all regulated establishments engaged in the manufacture, preparation, compounding, or propagation of drug products. These listings provide data for most other Human Drug Program projects, and other Federal agencies as well. These agencies include the Drug Enforcement Administration, the Social and Rehabilitation Service, the Health Care Financing Administration, and the Environmental Protection Agency.

## New Drug Evaluation

The mission of this project is to ensure that new drugs are evaluated and approved for marketing on the basis of adequate evidence of safety and effectiveness; ensure that new drugs are properly labeled; ensure that once marketed, experience in use confirms this judgment; and ensure that clinical investigations of new drugs properly safeguard the rights of human subjects while developing high quality data on safety and efficacy. To this end, project activities include evaluating the safety and efficacy of new drugs, conducting research which supports new drug evaluations, and developing new guidelines, regulations, and labeling. The project also responds to requests for information, works to improve the management of the new drug evaluation process, and evaluates the abuse potential of investigational drugs, new drugs and marketed drugs. Because its activities extend into other drug-related areas, New Drug Evaluation works in close conjunction with most other Human Drug Program projects.

## Poison Control

The National Clearinghouse for Poison Control was established in 1957 and now services a network of over 580 Centers. It provides toxicity and treatment information about household products and medicines to the network of Poison Control Centers, maintains surveillance of the problem by compiling an information base of poisoning reports in a computer system, conducts research on poisoning prevention and improved treatment procedures, and conducts educational programs about poisoning prevention.

The project assists the Poison Prevention Week Council in national poison prevention activities, including educational programs and information for National Poison Prevention Week. It supplies data and information about injuries from the ingestion of household products to the Commissioners of the Consumer Product Safety Commission for establishing regulatory priorities under the Poison Prevention Packaging Act. In addition, the project makes case report data available to the EPA for determining the prevalence and hazards of misusing products covered under the Federal Insecticide, Fungicide, and Rodenticide Act. The Poison Control project also supplies information and data to other FDA Human Drug Program projects, including Drug Quality Assurance, OTC Drug Evaluation, Drug Experience and Trend Analysis and Prescription Drug Labeling.

# NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Jefferson, Arkansas 72079

Locator: 501-541-4611
FTS-542-4611

Information: 501-541-4503
FTS-542-4503

Organization....................page 88
Statutory Authorities...........page 93
Toxics-Related Activities.......page 94

The National Center for Toxicological Research (NCTR) was established in early 1971 and became operational in mid-1972 as a joint venture of the Federal Food and Drug Administration and the Environmental Protection Agency. The Center was created to help provide a better understanding of the relationships of the chemicals in the environment and the possible adverse effects of these chemicals. NCTR has since developed an advanced scientific program of toxicological experimentation which is supported by its own research laboratories and other related facilities. Research activities are directed toward four specific goals:

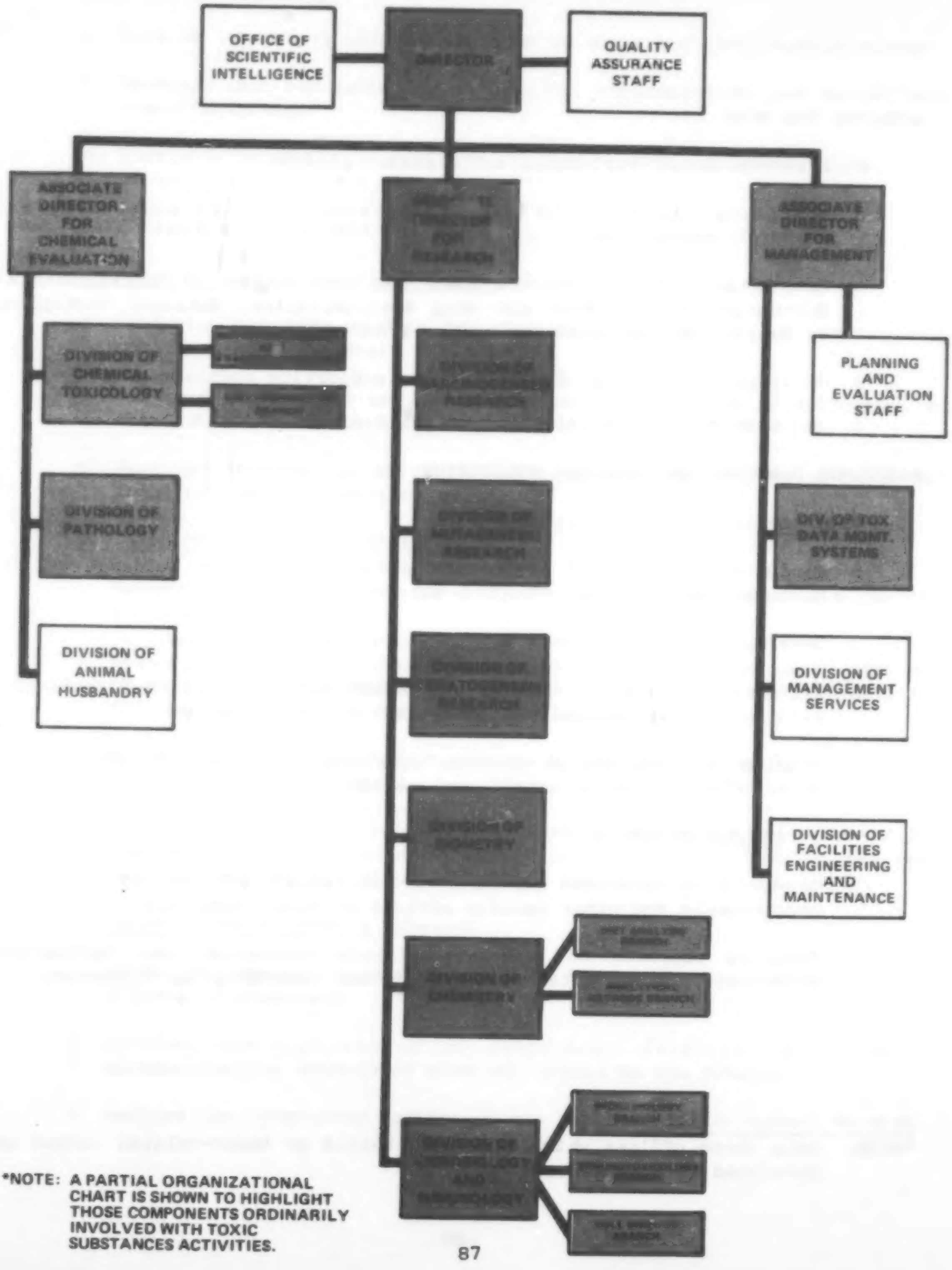
- Determination of adverse effects resulting from long-term, low level exposure to various chemical substances.
- Development of experimental data to facilitate extrapolation of laboratory results to man.

- Determination of basic biological processes in animals to provide a more accurate extrapolation of laboratory results to humans.
- Development of improved methods and testing protocols for evaluating the relative safety of chemical substances.

To this end, the Food and Drug Administration is responsible for administering the Center in such a way that it is responsive to the needs of the signatory agencies (EPA and HHS) when their programs require research and development suitable to the Center's capabilities. In addition, other agencies, universities, and industry may also participate to the extent that their expertise is required.

Guidelines for the Center are developed by an Interagency Policy Board, with voting members from HHS and EPA and nonvoting members from The Council on Environmental Quality (CEQ). The Policy Board provides interagency reviews of research programs conducted by the Center to ensure that programs are oriented toward the needs of the agencies. Specifically, the Policy Board recommends program policies to the Director, reviews budgetary requirements, evaluates research results, recommends appropriate management policy, approves key appointments, and advises agency heads on matters concerning the Center.

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
## FOOD AND DRUG ADMINISTRATION
# NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
## ORGANIZATIONAL CHART *


OFFICE OF SCIENTIFIC INTELLIGENCE
DIRECTOR
QUALITY ASSURANCE STAFF
ASSOCIATE DIRECTOR FOR CHEMICAL EVALUATION
ASSOCIATE DIRECTOR FOR RESEARCH
ASSOCIATE DIRECTOR FOR MANAGEMENT
DIVISION OF CHEMICAL TOXICOLOGY
BRANCH
DIVISION OF PATHOLOGY
DIVISION OF ANIMAL HUSBANDRY
DIVISION OF CARCINOGENESIS RESEARCH
DIVISION OF MUTAGENESIS RESEARCH
DIVISION OF TERATOGENESIS RESEARCH
DIVISION OF BIOMETRY
DIVISION OF CHEMISTRY
DIET ANALYSIS BRANCH
ANALYTICAL METHODS BRANCH
DIVISION OF MICROBIOLOGY AND IMMUNOLOGY
MICROBIOLOGY BRANCH
IMMUNOTOXICOLOGY BRANCH
CELL BIOLOGY BRANCH
PLANNING AND EVALUATION STAFF
DIV. OF TOX. DATA MGMT. SYSTEMS
DIVISION OF MANAGEMENT SERVICES
DIVISION OF FACILITIES ENGINEERING AND MAINTENANCE

*NOTE: A PARTIAL ORGANIZATIONAL CHART IS SHOWN TO HIGHLIGHT THOSE COMPONENTS ORDINARILY INVOLVED WITH TOXIC SUBSTANCES ACTIVITIES.

# ORGANIZATION *

DIRECTOR FOR NCTR

- Oversees Center activities and research efforts.
- Maintains liaison with representatives from the scientific and research communities.
- Coordinates NCTR programs with the activities of Environmental Protection Agency, Food and Drug Administration, National Institutes of Health, and National Toxicology Program.
- Monitors performance of the Center's supporting contractors.
- Implements Departmental research policies.

ASSOCIATE DIRECTOR FOR CHEMICAL EVALUATION

Division of Chemical Toxicology

- Conducts research and evaluation efforts under the guidance of the National Chemical Toxicological Testing Program.
- Develops improved methods for toxicological evaluations.
- Performs research on chronic and subchronic toxicological conditions with particular emphasis on dose-response relationships.
- Studies the connection between nutrition and toxicity and advises other NCTR offices on nutritional matters.

Nutrition Branch

- Conducts chronic and subchronic laboratory studies to determine carcinogenic and other harmful effects of toxic chemicals.
- Performs research on how diet affects biological and biochemical processes that may alter carcinogenic and toxicological responses.

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*NOTE: Only those offices which deal with toxics or toxic-related issues are developed in this section.

### Diet Preparation Branch

- Mixes chemical compounds into animal feed for use in experimental diet studies.

### Division of Pathology

- Studies laboratory animal responses to toxic and carcinogenic agents.
- Develops improved pathology techniques, methodologies, and morphologic classifications.
- Provides scientific guidance to other NCTR programs concerning pathology.

## ASSOCIATE DIRECTOR FOR RESEARCH

### Division of Carcinogenesis Research

- Conducts long-term studies for evaluating the effects of carcinogenic substances on laboratory animals.
- Conducts experiments to determine dose-time response relationships of chemical toxicants in laboratory animals.
- Develops information on toxic responses and designs new methods for applying toxicity assessments.

### Division of Mutagenesis Research

- Estimates the risk to humans from exposure to chemicals in the environment.
- Develops methods to measure both microlesions (single gene mutations or small deletions) and macrolesions (serious chromosomal aberrations) for use in toxicology and safety evaluations.
- Works to improve short-term bioassays for identifying the effects of toxic substances on genes.
- Focuses research on developing reliable and economical methods for evaluating the genotoxic potential of chemicals. Results are then used to identify the chemical risk to humans.

### Division of Teratogenesis Research

- Works to develop improved methods for evaluating adverse health effects of chemicals.
- Studies the application of laboratory findings to humans in determining the effects of chemical agents on the fetus.
- Manages the teratology section of the National Toxicological Program.

best copy available

- Currently conducts four major projects: the Behavioral Teratology Collaborative Study; Reliability of Animal Models in Teratology; Development and Use of Mathematical Extrapolation Models in Teratogenesis and Utility of Fetal Histopathology in Teratology Testing.

## Division of Biometry

- Performs statistical analyses to support NCTR experimental programs.

- Develops statistical hypotheses for researchers and provides criteria for establishing the validity of statistical analyses performed at the Center.

- Maintains liaison with Environmental Protection Agency, Food and Drug Administration, National Institutes of Health, and other organizations concerned with biometric applications to toxicology.

## Division of Chemistry

- Develops chemical procedures for performing trace analysis of carcinogens, teratogens, mutagens, toxicants, and other substances.

- Studies chemical behavior, dosage forms, safe use and disposal of chemicals.

- Develops data bases to assist in the compliance with good laboratory practice (GLP) requirements.

### Diet Analysis Branch

- Develops analytical methods to ensure nutritional integrity and absence of harmful substances in animal diets.

- Provides radioimmunoassay services.

### Analytical Methods Branch

- Develops techniques for improving the accuracy of trace-level chemical analyses.

## Division of Microbiology and Immunology

### Microbiology Branch

- Develops improved procedures for using microorganisms to assess chemical toxicity.

- Provides microbiological services to support NCTR's toxicological operations.

### Immunotoxicology Branch

- Conducts research on immunotoxicants that suppress reactions to harmful organisms.
- Assesses the impact of chemical agents on natural defense and repair mechanisms.

### Cell Biology Branch

- Analyzes cells from toxically damaged tissues.
- Develops techniques for early diagnosis of carcinogenic growths.
- Examines biological changes resulting from exposure to toxic chemical compounds.

## ASSOCIATE DIRECTOR FOR MANAGEMENT

### Division of Toxic Data Management Systems

- Operates the Toxic Data Management System (TDMS) in conjunction with National Cancer Institute and National Institutes of Health.
- Assists EPA Office of Testing and Evaluation in developing an automated data system, in accordance with TSCA guidelines.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Division of Carcinogenesis Research | 501-541-4204<br>FTS: 8-542-4204 | HFT-110 |
| Division of Mutagenesis Research | 501-541-4496<br>FTS: 8-542-4496 | HFT-120 |
| Division of Teratogenesis Research | 501-541-4304<br>FTS: 8-542-4304 | HFT-130 |
| Division of Biometry | 501-541-4519<br>FTS: 8-542-4519 | HFT-140 |
| Division of Chemistry | 501-541-4556<br>FTS: 8-542-4556 | HFT-150 |
| Diet Analysis Branch | 501-541-4446<br>FTS: 8-542-4446 | HFT-152 |
| Spectroscopic Techniques Branch | 501-541-4368<br>FTS: 8-542-4368 | HFT-154 |

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Division of Microbiology and Immunology | 501-541-4449<br>FTS: 8-542-4449 | HFT-160 |
| Microbiology Branch | 501-541-4450<br>FTS: 8-542-4450 | HFT-162 |
| Immunotoxicology Branch | 501-541-4491<br>FTS: 8-542-4491 | HFT-163 |
| Cell Biology Branch | 501-541-4574<br>FTS: 8-542-4574 | HFT-164 |
| Division of Chemical Toxicology; Nutrition Chemical and Evaluation Branch | 501-541-4551<br>FTS: 8-542-4551 | HFT-210 |
| Diet Preparation Branch | 501-541-4385<br>FTS: 8-542-4385 | HFT-213 |
| Division of Pathology | 501-541-4185<br>FTS: 8-542-4185 | HFT-230 |

# STATUTORY AUTHORITIES

NCTR received its authority through President Nixon's announcement on January 27, 1971, establishing the research center at Pine Bluff, Arkansas. Its implementing authority originates in an Interagency Agreement between the Department of Health, Education, and Welfare (now Health and Human Services) and the Environmental Protection Agency signed on April 1, 1971. The Interagency Agreement establishes the Center's mission, functions, structure, and research responsibilities. Statutory authority enabling the Department of Health, Education, and Welfare and the Environmental Protection Agency to direct the Center's activities resides in the Presidential letter and in the general legislative requirements assigning to the Agencies toxics-related research responsibilities. These Acts include the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 348, 355; the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135; the Clean Air Act, 42 U.S.C. § 1857; the Solid Waste Disposal Act, 42 U.S.C. § 3251; and the Federal Water Pollution Control Act, 33 U.S.C. § 1151.

# TOXICS-RELATED ACTIVITIES*

## Research Experiments

As a research facility, a principal activity of NCTR is the performance of experiments in toxics-related areas, including carcinogenesis, mutagenesis, and teratogenesis research. Experiments in other toxic fields are also conducted by the respective Divisions within NCTR: Biometry, Chemistry, Microbiology and Immunology, Chemical Toxicology and Pathology. For a listing of specific experiments, contact the Planning and Evaluation Staff at NCTR (501) 541-4503 or FTS-542-4503.

## Toxic Data Management Systems

In a joint effort with the National Cancer Institute (NCI) and the National Institutes of Health (NIH), NCTR developed the Toxic Data Management Systems (TDMS) in 1977 to address data processing and reporting problems of agencies involved in toxicological research. This Division provides a number of different support services: documentation of chemical compounds; analysis

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

# *NATIONAL INSTITUTES OF HEALTH*

Public Health Service
Department of Health and Human Services
Bethesda, MD 20014

Locator: 301-496-2351
Information: 301-496-2535

The National Institutes of Health (NIH), an agency of the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare), works to improve human health by acquiring new scientific knowledge. Specifically, NIH

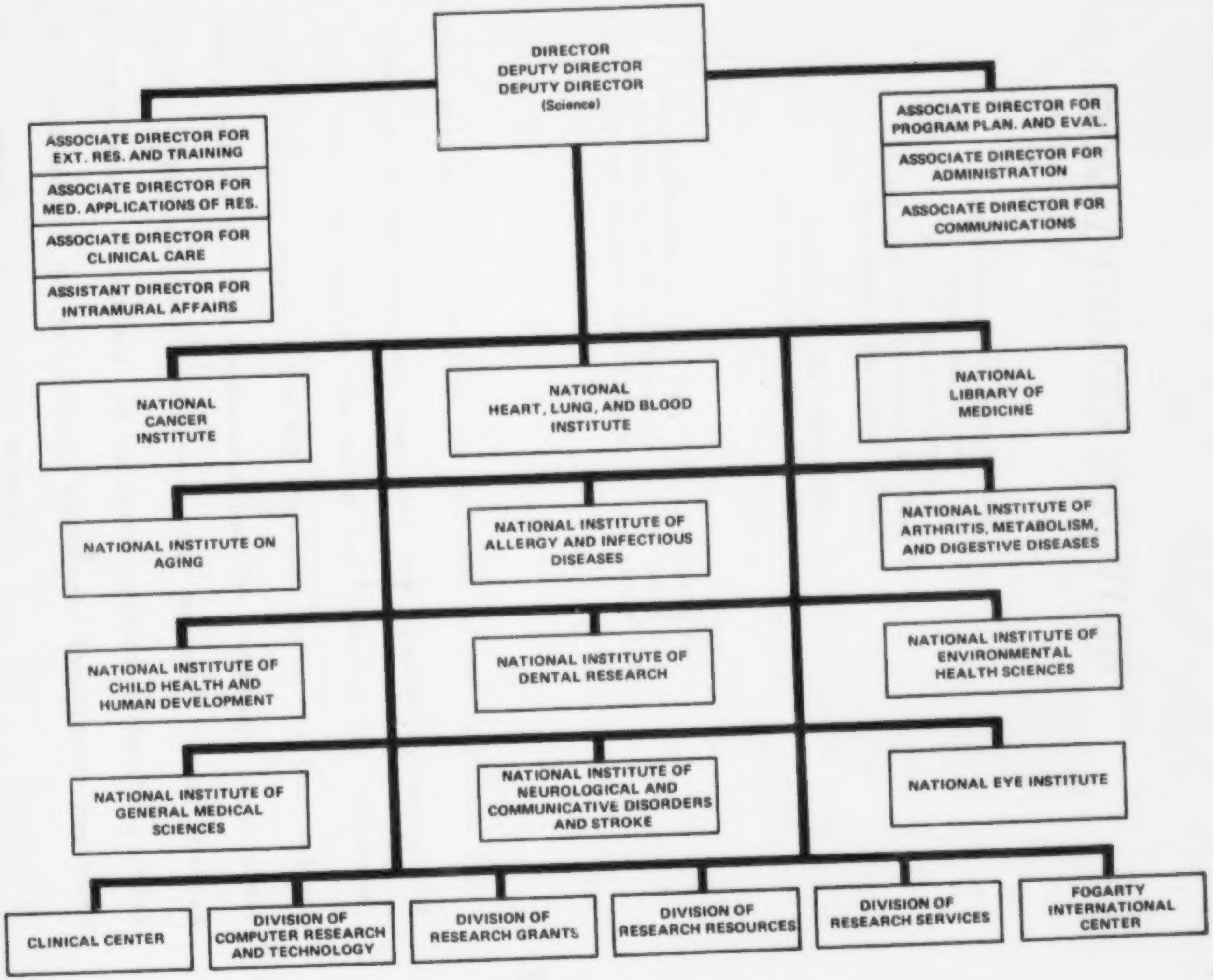
- conducts biomedical research in its own laboratories;
- provides grants to nonprofit organizations and institutions for research and for medical education, including improvement or construction of library facilities, buildings, equipment and other resources;
- provides grants for the training of research investigators; and
- promotes effective ways to communicate biomedical information to scientists, health practitioners, and the public.

To carry out these functions, NIH is organized into 11 research Institutes, 4 Divisions, and the National Library of Medicine. The organization also includes a research hospital called the Clinical Center, and the Fogarty International Center, which fosters international biomedical exchange and which provides facilities for foreign scholars in residence. NIH is headquartered in Bethesda, Maryland. However one of its Institutes--the National Institute of Environmental Health Sciences--is at Research Triangle Park, North Carolina.

This publication will focus on the responsibilities and activities of two of the NIH Institutes--the National Cancer Institute and the National Institute of Environmental Health Sciences.

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
## NATIONAL INSTITUTES OF HEALTH
## PUBLIC HEALTH SERVICE

## ORGANIZATIONAL CHART


DIRECTOR
DEPUTY DIRECTOR
DEPUTY DIRECTOR
(Science)
ASSOCIATE DIRECTOR FOR EXT. RES. AND TRAINING
ASSOCIATE DIRECTOR FOR MED. APPLICATIONS OF RES.
ASSOCIATE DIRECTOR FOR CLINICAL CARE
ASSISTANT DIRECTOR FOR INTRAMURAL AFFAIRS
ASSOCIATE DIRECTOR FOR PROGRAM PLAN. AND EVAL.
ASSOCIATE DIRECTOR FOR ADMINISTRATION
ASSOCIATE DIRECTOR FOR COMMUNICATIONS
NATIONAL CANCER INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL LIBRARY OF MEDICINE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
NATIONAL EYE INSTITUTE
CLINICAL CENTER
DIVISION OF COMPUTER RESEARCH AND TECHNOLOGY
DIVISION OF RESEARCH GRANTS
DIVISION OF RESEARCH RESOURCES
DIVISION OF RESEARCH SERVICES
FOGARTY INTERNATIONAL CENTER

# NATIONAL CANCER INSTITUTE

Department of Health and
Human Services
Public Health Service
National Institutes of Health
Bethesda, Maryland 20205

Locator: 301-496-4000
Information: 301-496-6641

Organization......................page 103
Statutory Authorities.............page 106
Toxics-Related Activities.........page 109

The essential and continuing goal of the National Cancer Institute (NCI) is the same today as it was when the Institute was created by an Act of Congress 40 years ago: To develop the means for reducing the incidence, morbidity, and mortality of cancer. The NCI continues to be the lead Federal agency in cancer, responsible and accountable for the investment of progress toward that goal. The Institute coordinates the National Cancer Program (NCP), which encompasses a variety of programs sponsored by NCI, other branches of NIH, and Federal and non-Federal agencies. The Program has three major components: research, control, and support.

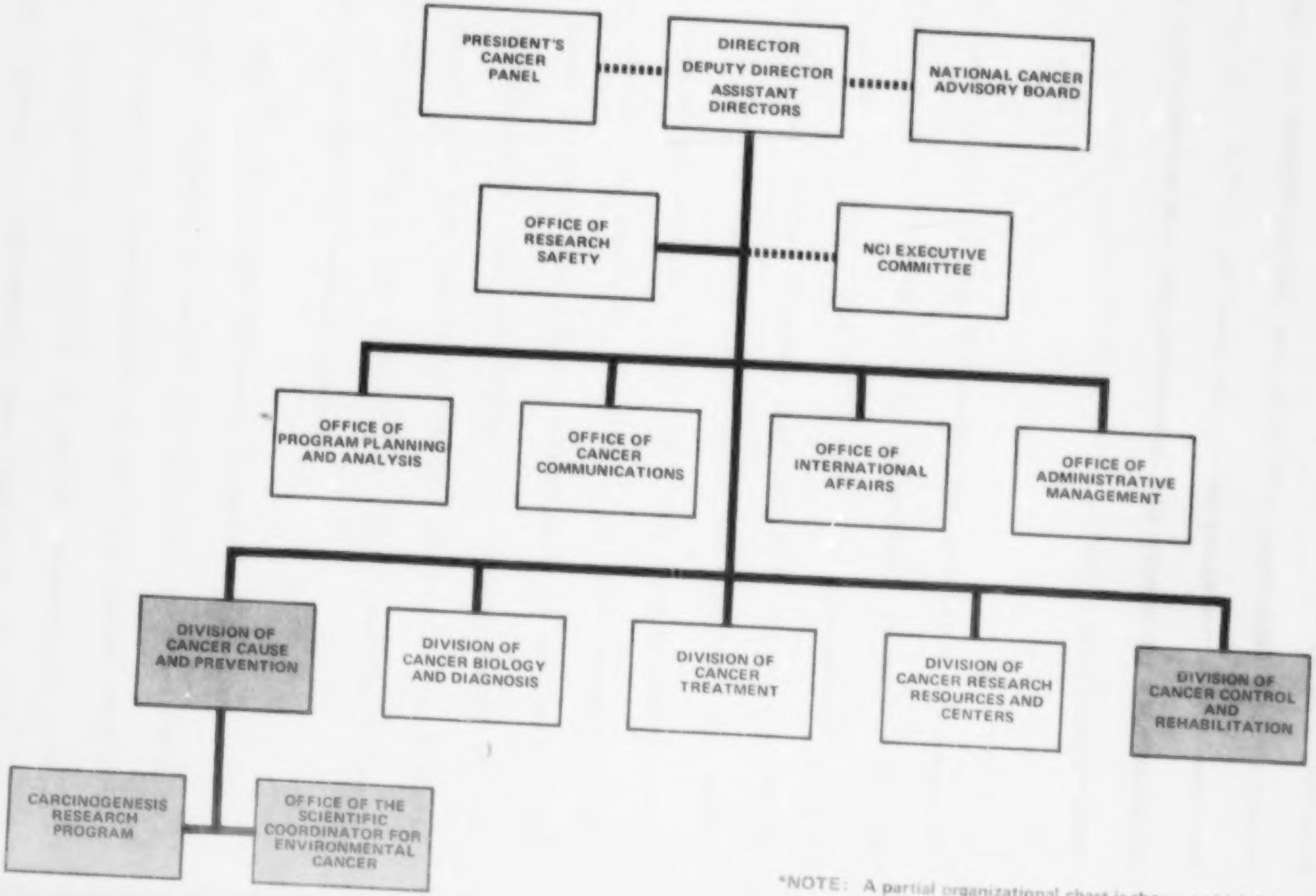
The first two components encompass the scientific and technical activities, while the support component includes those activities needed to carry out the research and control efforts effectively (e.g., construction and manpower development activities). The addition of cancer control responsibilities to NCI's research responsibilities and the specific emphasis placed on the expansion of comprehensive cancer centers as focal points for research, teaching, and demonstration, served to further emphasize the axiom that the ultimate purpose of disease research is to produce results that can be translated into improved methods for prevention and treatment of disease in people, and that the National Cancer Program would invest significant effort and resources in this area.

One important characteristic of the NCP since its inception has been the extensive and continuous participation of the biomedical community in the major planning efforts of the NCI. Beginning with the development of the first edition of the National Cancer Program Plan in 1972, periodic planning sessions have been held for the purpose of revising and updating the major recommendations for research and control activities. The general character of the Program has also become increasingly a product of more extensive and frequent interaction among Congress, the public, the biomedical community, and Federal agencies. In particular, the consistent and active roles of the President's Cancer Panel and the National Cancer Advisory Board have established a model for effective and productive relationships between national advisory committees and the Federal agency.

More specifically, NCI conducts and monitors research into the cause, prevention, diagnosis, and treatment of cancer and provides grants-in-aid to educational, public, or nonprofit institutions to perform cancer research. NCI also supports the professional education of cancer researchers through fellowships and project grants. Currently, the Institute is conducting studies on environmental carcinogens, including pesticides, aromatic amines (components of dyestuffs, hair dyes, and polymers), and halogenated aliphatic compounds (used in pesticides, solvents, and drycleaning agents). In other programs, the synergistic effects of physical environmental agents are under investigation, and food additives are being studied in terms of inhibiting environmental carcinogens. In addition, NCI acts as an information clearinghouse on cancer and has developed a data bank on international cancer research.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES
## PUBLIC HEALTH SERVICE
## NATIONAL INSTITUTES OF HEALTH
# NATIONAL CANCER INSTITUTE

## ORGANIZATIONAL CHART*


PRESIDENT'S CANCER PANEL
DIRECTOR DEPUTY DIRECTOR ASSISTANT DIRECTORS
NATIONAL CANCER ADVISORY BOARD
OFFICE OF RESEARCH SAFETY
NCI EXECUTIVE COMMITTEE
OFFICE OF PROGRAM PLANNING AND ANALYSIS
OFFICE OF CANCER COMMUNICATIONS
OFFICE OF INTERNATIONAL AFFAIRS
OFFICE OF ADMINISTRATIVE MANAGEMENT
DIVISION OF CANCER CAUSE AND PREVENTION
DIVISION OF CANCER BIOLOGY AND DIAGNOSIS
DIVISION OF CANCER TREATMENT
DIVISION OF CANCER RESEARCH RESOURCES AND CENTERS
DIVISION OF CANCER CONTROL AND REHABILITATION
CARCINOGENESIS RESEARCH PROGRAM
OFFICE OF THE SCIENTIFIC COORDINATOR FOR ENVIRONMENTAL CANCER

*NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# ORGANIZATION*

NOTE: NCI is currently undergoing reorganization. The materials presented here may be subject to change.

## DIVISION OF CANCER CAUSE AND PREVENTION

- Plans and directs a program of laboratory, field, and demographic research on the cause and natural history of cancer and the means for preventing cancer through in-house and contract research.
- Evaluates mechanisms of cancer induction by viruses and by environmental carcinogenic hazards.
- Serves as the focal point for the Federal Government on the synthesis of clinical, epidemiological, and experimental data relating to the cause of cancer.
- Advises the Director of NCI in evaluation of program activities relating to cancer control and on grants and grant applications as they relate to cancer cause and prevention.

### Carcinogenesis Research Program

- Plans, directs, and conducts a basic and applied research program on the role of chemical and physical causative factors and the prevention of carcinogenesis.
- Develops and conducts programs in the areas of carcinogenesis and related toxicology, metabolism, chemistry, cell biology, and experimental tumor pathology.

### Office of the Scientific Coordinator for Environmental Cancer

- Serves as a focal point for environmental cancer information and data through contract resources.
- Maintains the primary monitoring and collaborative function for coordinating the NCI/EPA Collaborative Program on Environmental Cancer and the NCI/NIOSH Collaborative Program on Occupational Carcinogenesis.
- Compiles and distributes publications on carcinogens in drinking water, carcinogens in air pollutants, carcinogens in food, diet, drugs, and cosmetics.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Conducts liaison activities for the National Cancer Program as it relates to the national effort on environmental and occupational cancer.

## DIVISION OF CANCER CONTROL AND REHABILITATION

- Plans, directs, and coordinates an integrated program of cancer control and rehabilitation activities with the goal of identifying, testing, evaluating, demonstrating, communicating, and promoting the widespread application of available and new methods for reducing the incidence, morbidity, and mortality of cancer.
- Serves as the focal point of a coordinated national effort to control cancer, involving all appropriate elements of the Department of Health, Education, and Welfare, other Federal agencies, State and local health departments, voluntary health agencies, and other elements of the private health community.
- In collaboration with the research divisions of the National Cancer Institute, identifies candidate control techniques and methods for inclusion in the field test and demonstration activities of the Division.
- Serves as the focal point of the National Cancer Institute for research in cancer rehabilitation.
- Participates in evaluation of and advises the Institute Director on program-related aspects of grants and contracts as they relate to cancer control and rehabilitation.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Director | 301-496-5615 | Building 31<br>Room 11A-52<br>Bethesda, MD 20205 |
| Division of Cancer Cause and Prevention | 301-496-6618 | Building 31<br>Room 11A-03<br>Bethesda, MD 20205 |
| Carcinogenesis Research Program | 301-496-1882<br>301-496-5946 | 7910 Woodmont<br>Landow Building<br>Room 8A-18<br>Bethesda, MD 20205 |

*FTS numbers are the same

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Scientific Coordinator for Environmental Cancer | 301-496-1625 | 7910 Woodmont<br>Landow Building<br>Room 36-37<br>Bethesda, MD 20205 |
| Division of Cancer Control and Rehabilitation | 301-427-8640 | Blair Building<br>Room 732<br>8300 Colesville Road<br>Silver Spring, MD 20910 |

# STATUTORY AUTHORITIES

## The National Cancer Institute Act

## Public Law 75-244

This Act, passed by Congress and signed by President Roosevelt in 1937, established the National Cancer Institute. The purpose of the Act was "to provide for, foster, and aid in coordinating research relating to cancer." The Act also established the precedent for providing grants-in-aid to non-Federal scientists engaged in cancer research and created the National Cancer Advisory Council. This Act has been superseded by the National Cancer Act of 1971, which is dealt with below.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 1 | Established NCI as a part of the Public Health Service. |
| sec. 2 (a,b) | Authorizes the Surgeon General to conduct and coordinate cancer research with other agencies, organizations, and individuals. |
| sec. 3 | Created the National Cancer Advisory Council, a six-member council composed of "leading medical or scientific authorities." |
| sec. 4 (a,b,c) | Authorizes the Council to evaluate cancer-related research projects, to make information regarding these projects available to the public, and to review all applications for grants-in-aid. |

## The Public Health Services Act of 1944

## Public Law 78-410    42 U.S.C. § 281

Enacted on July 1, 1944, the Public Health Services Act established the National Cancer Institute as a division of the National Institutes of Health and gave the Surgeon General broad powers to foster research relating to health and disease. The Act also consolidated many NCI revisions into this single law.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 401 | "The NCI shall be a division of the National Institutes of Health." |
| sec. 402 | Foster and coordinate cancer research. |
| sec. 403 | Transfers statutory authority for the administration of NCI from the National Cancer Institute Act of 1937 to the Public Health Services Act of 1944. |
| sec. 404 | Transfers statutory authority for the National Cancer Advisory Council from the National Cancer Institute Act of 1937 to the Public Health Services Act of 1944. |

## The National Cancer Act of 1971

Public Law 92-218 42 U.S.C. §§ 281-286

This Act broadened the responsibilities and authorities of the NCI Director and initiated the National Cancer Program. The Act also created the international cancer research data bank and established a three-member President's Cancer Panel and the National Cancer Advisory Board.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 3(a) | Amends Part A of Title IV of the Public Health Services Act by adding after section 406 the following section regarding the "National Cancer Program." |
| sec. 407(a) | Authorizes the Director of NCI to coordinate all NIH activities related to cancer. |
| sec. 407(b)(1) | Initiates an expanded, intensified, and coordinated cancer research program. |
| sec. 407(b)(4) | Establishes "an international cancer research data bank to collect, catalog, store, and disseminate information regarding the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country." |

| | |
|---|---|
| sec. 407(c)(1) | Establishes the President's Cancer Panel, a three-member panel appointed by the President to appraise the National Cancer Program. |
| sec. 408 | Provides for the establishment of new cancer research and demonstration centers. |

## The National Cancer Act Amendments of 1974

### Public Law 93-352   42 U.S.C. §§ 281-286

In addition to authorizing appropriations for Fiscal Years 1975-77, these amendments brought about improvements and changes in the National Cancer Program. Also, they established guidelines for the dissemination and interpretation of information on cancer research, directed the NCP to explore the role of nutrition in the treatment, rehabilitation, and causation of cancer, and removed the limits on the number of comprehensive cancer centers that could be initiated by the NCI.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 103 | Directs NCI to include into the data bank information regarding "nutrition programs for cancer patients and the relationship between nutrition and cancer." |
| sec. 108 (b)(1) | Authorizes NCI to contract for a specific program "to disseminate and interpret, on a current basis, for professionals and other health officials, scientists, and the general public," information on the cause, prevention, diagnosis, and treatment of cancer. |

# TOXICS-RELATED ACTIVITIES*

The broad goals of NCI's toxics programs are to identify environmental carcinogens, to establish and measure the relation between carcinogens and the incidence of cancer, and to prevent cancer through educational and other programs. NCI is a major source of information on cancer incidence and mortality for researchers studying environmental carcinogens. Through its programs, the NCI seeks to develop knowledge on the causes of cancer from epidemiological studies correlating exposure amounts with the incidence of cancer; from bioassays of animals and in vitro systems; from animal-human correlations developed by comparing bioassays and epidemiological studies; and from studying pharmacological metabolic relations in various species.

The Institute's programs touch on a broad range of cancer-related areas of study: the susceptibility of fetuses and children to environmental agents; cancer mapping, or the relation of cancer incidence to potential environmental causes; correlation studies linking localized mortality rates with corresponding environmental data; the connection of cancer incidence to occupation; and special studies to determine the factors at work in communities with high rates of cancer. In addition, the NCI conducts programs studying the relationships between reserpine and breast cancer, fluorides and generalized cancer, chlorinated water and increased rates of cancer, and industrial hazards and cancer. NCI is also investigating a number of environmental contaminants, such as asbestos, TRIS, and vinyl chloride.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omission to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

## The Cancer Control Program

The Cancer Control Program, established in 1972, has numerous activities aimed at controlling the occurrence and impact of the major causes of cancer. Educational programs have been developed for health professionals, the medical community, and the general public. The Cancer Control Program conducts conferences for analyzing and determining the scientific basis of recommendations for cancer screening programs and provides research grants to individuals or institutions studying methods of cancer control.

Through an agreement with the Occupational Safety and Health Administration (OSHA), NCI has instituted an occupational cancer information and alert program. Among other studies, this program has examined the carcinogenic effects of diethylstilbestrol (DES) and other synthetic estrogens used by women during pregnancy.

Under the Cancer Control Program, an information network on the diagnosis and treatment of specific types of cancer is being developed. This network will link hospitals and physicians at the community level with selected primary hospitals.

## The Cancer Centers Program

The Cancer Centers Program was founded in 1961 for the development and dissemination of information on the most effective methods of cancer prevention, diagnosis, treatment, and rehabilitation. The emphasis of the program is on providing financial support to institutions engaged in multidisciplinary research. The Program seeks to attract physicians and scientists of diverse backgrounds in order to develop a broad base of information on cancer control activities.

## The Diet, Nutrition, and Cancer Program

The Diet, Nutrition, and Cancer Program was formed in 1974 to conduct research and disseminate information on nutrition for cancer patients and on the relation between nutrition and cancer.

## Supporting Programs

The major objectives of the Carcinogenesis Research Program are to conduct and support research to identify the determinants of cancer in man, to understand their mechanisms of action and to develop and evaluate measures that will arrest, reverse, or otherwise interfere with the initiation or progression of the cancer process. These objectives include the development of improved methods for removing hazardous chemicals from the environment; to devise better means for hosts to detoxify environmental agents; to analyze synergistic actions among animals, viruses, and physical carcinogens; and to develop rapid and sensitive bioassays.

Under the Carcinogenesis Testing Program, chemicals are studied for their cancer-causing potential. The program develops bioassays for the *in vivo* and *in vitro* testing of chemical and physical agents in the environment and for carcinogenic and cocarcinogenic effects. Also, research is conducted on the development and evaluation of standardized methods, designs, and models for *in vivo* and *in vitro* carcinogenesis testing, related toxicology, and tumor pathology.

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The Frederick Cancer Research Center tests the cancer-causing potential of chemicals and viruses in laboratory animals. Research on chemicals involves bioassay for carcinogenicity and some mechanism studies.

The Division of Cancer Treatment studies tumor therapy and the induction of tumors in primates by antitumor agents and other materials.

# NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Department of Health and
Human Services
Public Health Service
National Institutes of Health
P.O. Box 12233
Research Triangle Park, N.C. 27709

Information: 919-541-3345
FTS: 629-3345

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The National Institute of Environmental Health Sciences (NIEHS) has the broadest responsibility among Federal agencies for the support of research, and the training of research manpower, in the area of effects of chemical and physical environmental agents on human health. The goal of NIEHS is to provide the scientific information base, advanced scientific methodology, and trained scientific manpower to reach an understanding of the total impact of environmental factors on human health. The output of NIEHS programs is intended to aid those agencies and organizations, both public and private, with responsibilities for developing and instituting pollution control regulations or therapeutic measures.

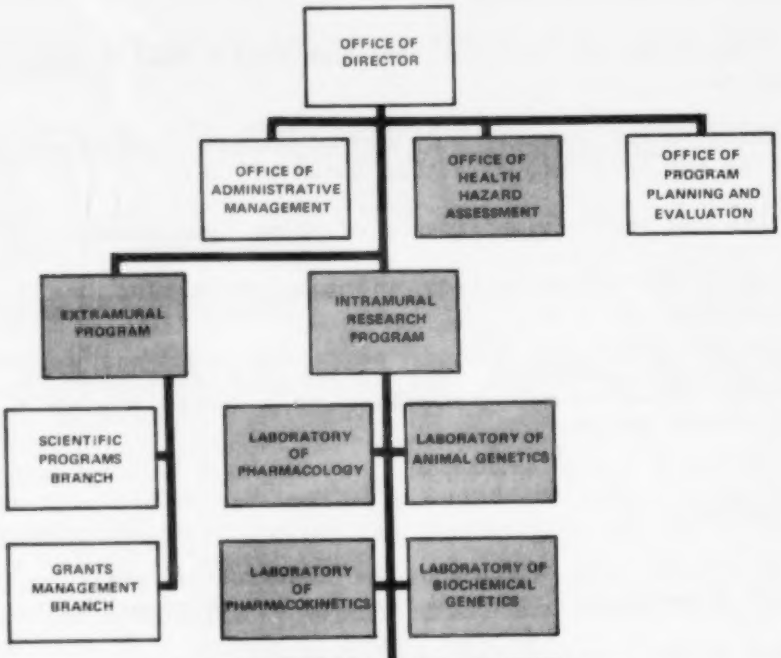
NIEHS pursues its mission by supporting training in the areas of environmental toxicology, environmental pathology, environmental mutagenesis, and environmental epidemiology, and by funding basic and applied research on the consequences of the exposure of man and other biological systems to potentially toxic or harmful agents in the environment. In its research, NIEHS attempts to learn: (1) how and where potentially harmful environmental agents are released into the environment; (2) how these agents move, and possibly change as they move, through the environment; (3) how they affect man and other biological systems in the environment; (4) the extent of exposure of various population groups, especially sensitive populations, to these agents; (5) the effects these agents, by themselves and in combination with other agents cause in the environment; (6) what happens in biological systems after exposure to hazardous agents; and (7) what diseases are caused or aggravated. Supplementary to these activities, NIEHS supports efforts to identify hazardous environmental agents before they are released into the environment. These efforts include the development, testing, and validation of biological test systems that can be used to predict the toxicity in man that would occur from exposure to environmental factors.

Thus, NIEHS is a research organization whose goal is to provide knowledge about the impact of environmental factors on human health in order to aid those agencies charged with developing and instituting control or therapeutic measures. Once this information base is developed, it is transmitted to regulatory agencies, other Government agencies, the medical community, industry, and the general public for subsequent action. After information on a disease endpoint is generated, it is supplied to the appropriate institutes. Accordingly, results of NIEHS research form the basis for preventive programs for environmentally related diseases and for action by regulatory agencies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

# NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

## ORGANIZATIONAL CHART*


OFFICE OF DIRECTOR
OFFICE OF ADMINISTRATIVE MANAGEMENT
OFFICE OF HEALTH HAZARD ASSESSMENT
OFFICE OF PROGRAM PLANNING AND EVALUATION
EXTRAMURAL PROGRAM
INTRAMURAL RESEARCH PROGRAM
SCIENTIFIC PROGRAMS BRANCH
GRANTS MANAGEMENT BRANCH
LABORATORY OF PHARMACOLOGY
LABORATORY OF ANIMAL GENETICS
LABORATORY OF PHARMACOKINETICS
LABORATORY OF BIOCHEMICAL GENETICS
LABORATORY OF REPRODUCTIVE AND DEVELOPMENTAL TOXICOLOGY
LABORATORY OF MOLECULAR GENETICS
LABORATORY OF ORGAN FUNCTION AND TOXICOLOGY
LABORATORY OF PULMONARY FUNCTION AND TOXICOLOGY
LABORATORY OF BEHAVIORAL AND NEUROLOGICAL TOXICOLOGY
LABORATORY OF ENVIRONMENTAL CHEMISTRY
BIOMETRY BRANCH
COMPARATIVE MEDICINE BRANCH
LABORATORY OF ENVIRONMENTAL BIOPHYSICS
ENVIRONMENTAL BIOLOGY BRANCH

***NOTE:** A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances research.

# ORGANIZATION*

OFFICE OF HEALTH HAZARD ASSESSMENT

- Plans, develops, and directs the Institute's health hazard assessment activities.
- Identifies environmental and technological developments having the potential for adversely affecting human health.
- Evaluates the health significance of these developments.
- Recommends Institute policy and program action based upon these assessments.
- Serves as the Institute focal point for functions of this kind, including managing its functions as a World Health Organization Collaborating Center.

EXTRAMURAL PROGRAM

- Plans, directs, and evaluates the Institute's grant program, which supports research and research training in environmental health.
- Develops program priorities and recommends funding levels to assure maximum use of available resources in attainment of Institute objectives.
- Maintains an awareness of national research efforts and assesses the need for research and research training in environmental health.
- Prepares reports for and provides advice to the Institute Director, staff, and advisory groups to assist them in carrying out their responsibilities.
- Represents the Institute Director in the development and implementation of grant policy.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

## INTRAMURAL RESEARCH PROGRAM

- Plans and conducts the Institute's basic laboratory research program, which encompasses six major areas (pharmacology, environmental toxicology, biometry, environmental mutagenesis, environmental biophysics, and environmental chemistry) to ensure maximum utilization of available resources in the attainment of Institute objectives.
- Evaluates research efforts and establishes program priorities.
- Integrates ongoing and new research activities into the program structure.
- Collaborates with other Institute and NIH programs and maintains awareness of national research efforts in program areas.
- Provides advice to Institute Director and staff on matters of scientific interest.

### Laboratory of Pharmacology

- Examines the role of enzyme systems and toxication-detoxication of chemicals and explains organ, sex, strain, and species differences in toxic response to chemicals.
- Studies species differences in mechanism of and dose- and time-response relations for the actions of selected environmental hazards. Analyzes accumulation, distribution, and disposition of environmental chemicals in a variety of animal species.
- Analyzes accumulation, distribution, and disposition of environmental chemicals in a variety of animal species.
- Studies the interactions between toxic chemicals and between these and other normal body constituents or drugs to elucidate those interactions which may be adversely synergistic.
- Conducts selected studies in marine biology research, and coordinates and advises Institute staff and personnel of other organizations on marine biology research applicable to effects of environmental pollutants on man.

### Laboratory of Pharmacokinetics

- Plans and develops a focus at NIEHS for pharmacokinetics studies and collaborative efforts applying pharmacokinetic principles to understand where and why chemicals accumulate in living organisms and how these uptake, storage, and release processes are regulated or can be affected.
- Conducts studies to develop pharmacokinetic models for specific classes of chemicals in various species, and to develop strategies for extrapolating chemical behavior and toxicity from one species to another.

- o Develops and conducts studies on use of pharmacokinetics data to design better treatments for toxicities due to persistent chemicals, to evaluate body burdens of environmental chemicals, and to assess effects of different rates of exposure to environmental chemicals on toxicological outcomes.

- o Evaluates the role of metabolism in chemical accumulations among various species.

- o Establishes and maintains liaison with various groups in and out of Government using pharmacokinetic approaches in toxicological evaluations, preclinical drug testing, and clinical evaluation of drugs.

## Laboratory of Reproductive and Developmental Toxicology

- o Conducts research directed toward the understanding of mechanisms of reproductive, endocrinologic, and developmental toxicity produced by exposure to environmental agents.

- o Determines mechanisms of teratogenesis by using in vivo and in vitro techniques to develop more rapid and economical laboratory methods to predict teratogenesis.

- o Assesses environmental agents for their teratogenic potential.

- o Determines the molecular mechanisms underlying cellular differentiation.

- o Studies the molecular basis and determines the effects of environmental agents on the endocrine function of the reproductive system.

- o Analyzes the effects of prenatal exposure to hormonally active environmental agents on the development of reproductive tract function.

- o Determines the possible gestational origin of subtle toxic effects which do not become apparent until later in life.

- o Defines the effect of environmental agents on oogenesis and spermatogenesis.

- o Develops preclinical indicators of reproductive, endocrinologic, and developmental toxicity using in vitro cells and tissues, lower animals, and biochemical test systems.

## Laboratory of Organ Function and Toxicology

- o Studies the effects of environmental agents on renal, gastrointestinal, and hepatic functions.

- o Analyzes the mechanisms by which environmental agents alter the normal functions of these organ systems, including the roles of metabolism, endocrine factors, and toxicant-receptor interactions.

- Identifies sensitive factors of organ-specific toxicity useful in the early detection of toxicity or prediction of toxicity in experimental animals or humans.

- Develops methods for extrapolating data from experimental animal models to the estimation human risks from exposure to environmental agents.

Laboratory of Behavioral and Neurological Toxicology

- Plans, conducts, and coordinates studies on behavioral and neurological effects of environmental chemicals and stressors to develop better tests for these effects as well as to use behavioral and neurological indices as early warning systems for environmentally induced diseases.

- Evaluates behavioral and neurologic toxicity of selected chemicals and mixtures.

- Collaborates with other Institute programs to develop broad interdisciplinary programs for evaluating subtle effects of chemicals on the central and peripheral nervous systems.

- Serves as a national focus for activities in this research area, maintaining liaison and collaboration with other laboratories investigating the effects of chemicals on behavior.

Biometry Branch

- Provides statistical assistance in the design of Institute laboratory experiments and in the analysis of data from such experiments.

- Develops improved statistical techniques for estimating and determining the effects of environmental agents in laboratory test systems.

- Formulates mathematical and probability descriptions of dynamic processes in biology.

- Plans and conducts epidemiological studies for evaluating the role of environmental agents in human mortality and morbidity.

- Provides computational data processing services to Institute staff.

Laboratory of Environmental Biophysics

- Conducts studies of biological effects on humans of physical factors in the environment such as ionizing and nonionizing radiation, noise, heat, humidity, and vibration.

- Advises and collaborates with other Institute staff on studies involving the interaction of such physical stressors with other agents of concern.

- Uses sophisticated spectroscopic techniques to examine the biophysical mechanisms of chemical interactions with biological micromolecules, such as nucleic acid and proteins.

Laboratory of Animal Genetics

- Plans and conducts studies in somatic cell and higher eukaryotic systems to improve basic understanding of the mutation process at the cellular level with special reference to environmental mutagenesis.
- Develops and validates in vitro and in vivo test systems and models to facilitate extrapolation from experimental systems to humans.
- Develops improved models and measurements for monitoring populations for genetic change and damage.
- Evaluates approaches to the study of genetic damage in exposed human populations.
- Advises the staff of NIEHS and other entities on matters pertaining to cellular, eukaryotic, and population genetics and on the screening of environmental agents for mutagenicity.

Laboratory of Biochemical Genetics

- Investigates discrete and continuously variable characteristics as indicators of gene-controlled variation at the cell and organism level.
- Studies and evaluates potential indicators for suitability in detecting newly induced gene variation in whole animals and single cells.
- Conducts studies of enzymes demonstrable by electrophoresis, and explores their potential for indicating specific structural gene mutations.
- Explores gross characteristics, variations in which may signal particular gene mutations.
- Investigates experimentally genetic variation and mutation rate changes with respect to environmental health concerns.
- Provides consideration of health risks associated with mutagens in the environment.
- Advises NIEHS staff and staff of other organizations on matters relating to biochemical genetics.

Laboratory of Molecular Genetics

- Conducts studies in molecular, microbial, and somatic cell systems intended to improve understanding at the molecular level of the processes which either generate or protect against mutations following exposure to environmental agents.
- Develops and validates in vitro and in vivo test systems and models to detect mutagenic activity of environmental agents.

- Advises the staff of NIEHS and other entities on matters pertaining to molecular, microbial, and cellular genetics, and to the screening of environmental agents for mutagenicity.

Laboratory of Pulmonary Function and Toxicology

- Develops a central focus at NIEHS for research on effects of environmental chemicals and stressors on the lung.

- Conducts studies to develop new methods for assessing and detecting adverse effects of chemicals on the lung.

- Plans and conducts studies to elucidate the mechanisms by which chemicals and other stressors cause adverse effects on the lung.

- Investigates the nature of adverse effects of selected chemicals and mixtures of chemicals on the lung, and attempts to understand species differences in lung damage by selected chemicals.

Laboratory of Environmental Chemistry

- Develops analytical, biochemical, immunochemical, physical-organic, bioorganic, and bioinorganic chemical studies of environmental agents, biological materials, and their conversion products with emphasis on biomechanisms.

- Conducts collaborative research with other NIEHS laboratories and research programs in the chemistry of suspect agents.

- Develops, improves, and utilizes analytical methodology for specified agents as required by NIEHS laboratory and research programs.

- Synthesizes and characterizes both labeled and unlabeled suspect environmental agents and their conversion products to support diverse biological and nonbiological studies.

Comparative Medicine Branch

- Manages a program for environmental animal procurement, housing, and utilization and for sterile glassware and media preparation within the Institute.

- Develops, refines, and advises Institute scientists and programs of appropriate animal models for use in Institute research programs.

- Maintains collaborative laboratories in microbiology, experimental surgery, laboratory animal medicine, and mammalian reproduction.

- Plans and conducts research appropriate to these laboratory functions.

Environmental Biology Branch

- Assists and collaborates with NIEHS laboratories and research programs in the fields of inhalation toxicology, pathology, electron microscopy, and histology.

- Plans, conducts, and collaborates in basic and applied studies in these fields.

- Coordinates toxicologic bioassays on selected environmental chemicals.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Office of Health Hazard Assessment | 919-541-3471<br>FTS: 629-3471 | P.O. Box 12233<br>Research Triangle Park,<br>NC 27709 |
| Extramural Program | 919-755-4015<br>FTS: 672-4015 | " |
| Intramural Research Program | 919-541-3205<br>FTS: 629-3205 | " |
| Laboratory of Pharmacology | 919-541-3332<br>FTS: 629-3332 | " |
| Laboratory of Pharmacokinetics | 919-541-3205<br>FTS: 629-3205 | " |
| Laboratory of Reproductive and Developmental Toxicology | 919-541-3333<br>FTS: 629-3333 | " |
| Laboratory of Organ Function and Toxicology | 919-541-3376<br>FTS: 629-3376 | " |
| Laboratory of Behavioral and Neurological Toxicology | 919-541-3200<br>FTS: 629-3200 | " |
| Biometry Branch | 919-541-3441<br>FTS: 629-3441 | " |
| Laboratory of Environmental Biophysics | 919-541-3196<br>FTS: 629-3196 | " |
| Laboratory of Animal Genetics | 919-541-4690<br>FTS: 629-4690 | " |
| Laboratory of Biochemical Genetics | 919-541-3378<br>FTS: 629-3378 | " |

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Laboratory of Molecular Genetics | 919-541-2871<br>FTS: 629-2871 | P.O. Box 12233<br>Research<br>Triangle Park,<br>NC 27709 |
| Laboratory of Pulmonary Function and Toxicology | 919-541-3450<br>FTS: 629-3450 | |
| Laboratory of Environmental Chemistry | 919-541-3253<br>FTS: 629-3253 | " |
| Comparative Medicine Branch | 919-541-4473<br>FTS: 629-4473 | " |
| Environmental Biology Branch | 919-541-3267<br>FTS: 629-3267 | " |

# STATUTORY AUTHORITY

## Public Health Service Act

## Public Law 78-410    42 U.S.C. § 201

The authority under which the NIEHS supports and conducts its research is Section 301 of the Public Health Service Act, which gives the Secretary of HEW broad powers to conduct and support research relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 301(a) | Authorizes Surgeon General to conduct and "promote the coordination of research investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams." |
| sec. 301(b) | Authorizes the Surgeon General to make available any research facilities, public authorities, health officials, or scientists engaged in related fields of study. |

# TOXICS-RELATED ACTIVITIES*

## Toxicity Testing Systems

Development of testing systems and testing compounds for potential harmful effects currently involves many test procedures which are cumbersome and lack sensitivity. NIEHS is developing simple rapid processes and toxicity tests for detecting the ability of environmental agents to cause health effects such as cancer, genetic damage, birth defects, and organ damage. Studies on developing better test systems for detection of a variety of toxic endpoints are integral to the NIEHS component of the National Toxicology Program (NTP).

## Genetic Toxicology

NIEHS scientists are working to develop new mammalian test systems in an attempt to extrapolate from these experimental test systems to humans the mutagenic effects of chemicals. Underlying test development are basic research efforts on mutagenic mechanisms. Since mutagenic effects cannot be economically measured in man at the present time, experimental organisms ranging from microbes to mammals are currently used in test systems. The mutagenesis testing program is sequential, incorporating:

- o Rapid screening in simple, highly sensitive microbial systems.
- o *In vitro* mammalian cell systems and insect systems.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

o Development and validation of whole animal systems.

At full capacity, up to 1000 chemicals per year will be tested in microbial systems on contract, in direct support of the testing objectives of the National Toxicology Program.

## Reproductive and Developmental Toxicology and Teratology

Little is known about how the mother's pre- or postnatal exposure to drugs and common chemicals affects the development of offspring. NIEHS scientists are seeking to develop experimental models to study the mechanisms of such health effects and to predict damage for humans. Research emphasis includes: (1) development of model systems for man such as the mouse model for predicting and understanding toxic effects on the reproductive tract of DES and related hormonally active chemicals, (2) development of an interspecies *in vitro* fertilization assay for assessing human male fertility, (3) development and validation of an embryo culture system for predicting chemical teratogenesis, and (4) identification of biochemical markers, such as enzymes, which can indicate toxicity.

## Risk Assessment

The program in risk assessment is concerned with quantitative estimation of human health effects from exposure to environmental agents based upon laboratory, demographic, and epidemiological studies. Emphasis has been on carcinogenesis, but other toxic endpoints will be explored. Of principal concern is the problem of extrapolating animal dose-response relations from the high dose range to the lower dose levels corresponding to environmental exposures.

## Pharmacokinetics

This program is concerned primarily with developing better ways to study the rates and mechanisms of uptake, storage, persistence, metabolism, and excretion of environmental agents. Results in one species may be extrapolated to another; this program should be valuable as a predictive tool. Efforts in this program have been concentrated on developing pharmacokinetic models for the polychlorinated and polybrominated biphenyls that can be used for species-to-species extrapolation.

## Chronic Organ Toxicity

A major goal of this program is to identify early biochemical or physiological changes in organ function occurring during chronic exposure to toxic environmental agents. Identifying these changes will provide a better understanding of mechanisms of toxicity, as well as help predict early toxicity of environmental agents in humans. Emphasis has been on the renal, hepatic, and gastrointestinal organ systems.

## Pulmonary Toxicology

NIEHS seeks to obtain, through animal studies, information to provide a scientific basis for prevention of environmentally caused respiratory diseases. This program studies the structure and function of the normal respiratory tract, investigates mechanisms of injury and repair in respiratory tract tissues exposed to environmental toxins (e.g., air pollutants, asbestos, carcinogens), and studies the pathogenesis of specific disorders of pulmonary tissues (e.g., pulmonary fibrosis, emphysema).

## Epidemiology

A major goal of the NIEHS epidemiology program is to increase the effectiveness of human epidemiological studies by integrating them with many of the NIEHS internal biological research programs. Major emphasis is on an understanding of the origins of chronic diseases in humans, and their interactions with environmental factors, with particular emphasis in the areas of reproduction, genetics and disease susceptibility, and environmental carcinogenesis.

## Biochemical and Marine Pharmacology

Many chemicals are made toxic by biotransformation processes; furthermore, organ, strain, and species differences in toxicity often are related to quantitative differences in metabolism. These programs are concerned primarily with studying the role of chemical metabolism in mediation of toxicity. Emphasis is on characterizing the enzymes in liver, skin, intestine, and lung that make chemicals either more or less toxic, and defining how various factors such as age, sex, heredity, or other chemicals can alter the balance between the two types of enzyme systems. As an extension of these primarily mammalian investigations, studies are conducted on the uptake, distribution, metabolism, and excretion of pollutants by various marine species, and on the role of metabolism in the storage, chemical form, and toxicity of accumulated toxins in these species.

## Environmental Chemistry

This program combines environmental detection and analysis of chemicals with environmental toxicology. Particular emphasis is, and has been, devoted to various classes of halogenated aromatic chemicals. NIEHS scientists have defined in detail the physicochemical properties of the PCBs, PBBs, dioxins, furans, and chlorinated phenols; examined the relationship between chemical structure and biological fate and activity; synthesized major and proposed metabolites; and developed sensitive and specific analytical methodology for metabolite measurement.

## Molecular Biophysics

The objective of this program is to define toxicity by studying how chemicals interact at the molecular level (nucleic acids, proteins, membrane components). This research mandates use of sophisticated spectroscopic techniques such as electron spin resonance. Emphasis also is being placed on studying the synergistic effects of chemicals with physical factors. Biophysical approaches to toxicology are few in number, yet where applied, they have been most instructive.

# NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Department of Health and Human Services

Public Health Service

Center for Disease Control

HEADQUARTERS
Parklawn Building
5600 Fishers Lane
Rockville, Md 20857

Laboratories
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, Ohio 45226

Appalachian Laboratory for
Occupational Safety and Health
944 Chestnut Ridge Road
Morgantown, West Virginia 26505

Locator: 202-245-6296
Information: 301-443-2140

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The National Institute for Occupational Safety and Health (NIOSH) is the principal Federal agency involved in research to eliminate on-the-job hazards to the health and safety of the Nation's work force. Under the provisions of the Occupational Safety and Health Act (OSHA) of 1970 (Public Law 91-596), NIOSH was established within the Department of Health, Education, and Welfare (as of May 4, 1980--The Department of Health and Human Services (DHHS)) under the Center for Disease Control of the Public Health Service.

The major responsibility of NIOSH is to provide research and standards-setting support and recommendation for worker protection to the Department of Labor, Occupational Safety and Health Administration (OSHA) under the OSH Act of 1970 and the Mine Safety and Health Act of 1977, as amended. The Institute also has responsibility for the training of occupational health manpower.

Under the OSH Act, NIOSH conducts the research for occupational safety and health standards. These recommended standards are then sent to the Department of Labor, Occupational Safety and Health Administration, which is responsible for the final development, promulgation, and enforcement of the standards.

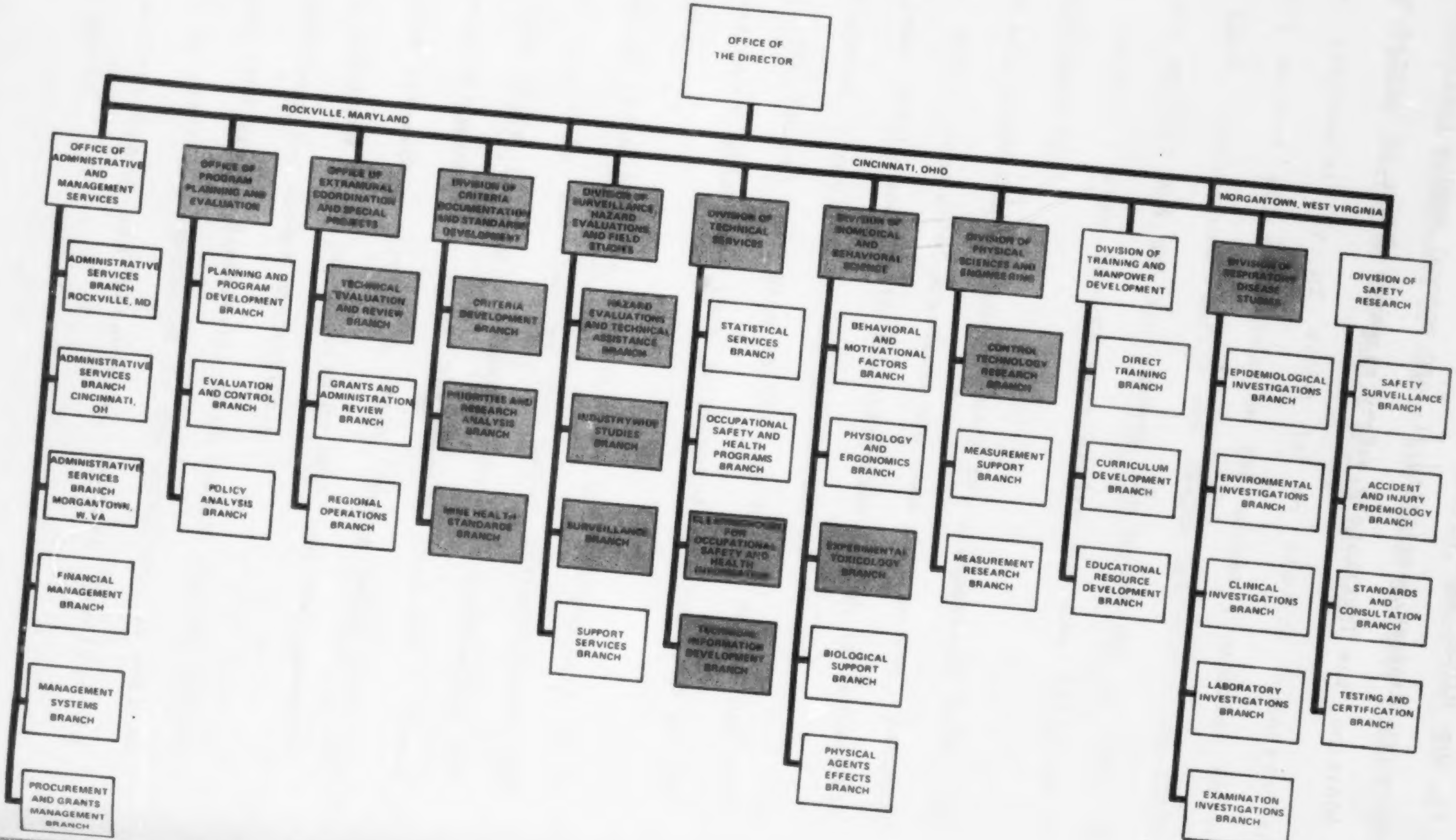
By authority of the Federal Coal Mine Health and Safety Act, NIOSH sets mandatory health standards which are then promulgated and enforced by the Department of the Interior.

NIOSH is located in three separate facilities. The headquarters is in Rockville, Maryland, where in addition to the major administrative and planning functions, the staff is also responsible for the preparation and update of the Criteria Documents and other information documents. These documents, which utilize research performed in NIOSH labs or under contract, serve as the basis for standards to be promulgated by OSHA, and for assessment of hazards and recommendations for worker protection.

The Institute's main labs are in Cincinnati, Ohio, where studies include the effects of exposure to hazardous substances in the workplace, as well as the psychological, motivational, and behavioral factors involved in occupational safety and health.

At the NIOSH laboratory in Morgantown, West Virginia, studies in respiratory disease, agricultural, and noncoal mining health are carried out. In addition, the Institute's safety research effort is located there.

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
## PUBLIC HEALTH SERVICE
## CENTER FOR DISEASE CONTROL
# NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
## ORGANIZATIONAL CHART*


OFFICE OF THE DIRECTOR
ROCKVILLE, MARYLAND
CINCINNATI, OHIO
MORGANTOWN, WEST VIRGINIA
OFFICE OF ADMINISTRATIVE AND MANAGEMENT SERVICES
ADMINISTRATIVE SERVICES BRANCH ROCKVILLE, MD
ADMINISTRATIVE SERVICES BRANCH CINCINNATI, OH
ADMINISTRATIVE SERVICES BRANCH MORGANTOWN, W. VA
FINANCIAL MANAGEMENT BRANCH
MANAGEMENT SYSTEMS BRANCH
PROCUREMENT AND GRANTS MANAGEMENT BRANCH
OFFICE OF PROGRAM PLANNING AND EVALUATION
PLANNING AND PROGRAM DEVELOPMENT BRANCH
EVALUATION AND CONTROL BRANCH
POLICY ANALYSIS BRANCH
OFFICE OF EXTRAMURAL COORDINATION AND SPECIAL PROJECTS
TECHNICAL EVALUATION AND REVIEW BRANCH
GRANTS AND ADMINISTRATION REVIEW BRANCH
REGIONAL OPERATIONS BRANCH
DIVISION OF CRITERIA DOCUMENTATION AND STANDARDS DEVELOPMENT
CRITERIA DEVELOPMENT BRANCH
PRIORITIES AND RESEARCH ANALYSIS BRANCH
MINE HEALTH STANDARDS BRANCH
DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS AND FIELD STUDIES
HAZARD EVALUATIONS AND TECHNICAL ASSISTANCE BRANCH
INDUSTRYWIDE STUDIES BRANCH
SURVEILLANCE BRANCH
SUPPORT SERVICES BRANCH
DIVISION OF TECHNICAL SERVICES
STATISTICAL SERVICES BRANCH
OCCUPATIONAL SAFETY AND HEALTH PROGRAMS BRANCH
CLEARINGHOUSE FOR OCCUPATIONAL SAFETY AND HEALTH INFORMATION
TECHNICAL INFORMATION DEVELOPMENT BRANCH
DIVISION OF BIOMEDICAL AND BEHAVIORAL SCIENCE
BEHAVIORAL AND MOTIVATIONAL FACTORS BRANCH
PHYSIOLOGY AND ERGONOMICS BRANCH
EXPERIMENTAL TOXICOLOGY BRANCH
BIOLOGICAL SUPPORT BRANCH
PHYSICAL AGENTS EFFECTS BRANCH
DIVISION OF PHYSICAL SCIENCES AND ENGINEERING
CONTROL TECHNOLOGY RESEARCH BRANCH
MEASUREMENT SUPPORT BRANCH
MEASUREMENT RESEARCH BRANCH
DIVISION OF TRAINING AND MANPOWER DEVELOPMENT
DIRECT TRAINING BRANCH
CURRICULUM DEVELOPMENT BRANCH
EDUCATIONAL RESOURCE DEVELOPMENT BRANCH
DIVISION OF RESPIRATORY DISEASE STUDIES
EPIDEMIOLOGICAL INVESTIGATIONS BRANCH
ENVIRONMENTAL INVESTIGATIONS BRANCH
CLINICAL INVESTIGATIONS BRANCH
LABORATORY INVESTIGATIONS BRANCH
EXAMINATION INVESTIGATIONS BRANCH
DIVISION OF SAFETY RESEARCH
SAFETY SURVEILLANCE BRANCH
ACCIDENT AND INJURY EPIDEMIOLOGY BRANCH
STANDARDS AND CONSULTATION BRANCH
TESTING AND CERTIFICATION BRANCH

*NOTE: A partial

# ORGANIZATION *

OFFICE OF PROGRAM PLANNING AND EVALUATION

- Plans and evaluates program.
- Plans and coordinates development of Institute strategy.

OFFICE OF EXTRAMURAL COORDINATION AND SPECIAL PROJECTS

- Advises the Institute of matters relating to the development and progress of Institute-supported grant research.
- Provides technical advice to the Director and other Institute offices.

Technical Evaluation and Review Branch

- Conducts or coordinates special short-term technical studies including evaluation of technical information transmitted to the Institute.
- Prepares background information on potentially hazardous substances in the occupational environment.
- Alerts the entire occupational health community to new information on potential occupational health hazards.

DIVISION OF CRITERIA DOCUMENTATION AND STANDARDS DEVELOPMENT

Criteria Development Branch

- Provides the scientific effort necessary to develop occupational health criteria.
- Coordinates the development and final approval of occupational health criteria and standards documents in cooperation with the U.S. Department of Labor.

Priorities and Research Analysis Branch

- Analyzes information on the exposure of workers to safety and health hazards.

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*NOTE: Only those offices which deal with toxics effects or toxics-related issues are developed in this section.

- Reviews the availability and adequacy of current literature to provide the basic information needed to prepare or update criteria and standards documents.

- Prepares and periodically revises a priority list of substances and industries for which various documents should be developed or revised.

- Conducts Special Occupational Hazard Reviews of potential workplace hazards where new evidence of a particular hazard is received, and prepares recommended emergency temporary standards as appropriate.

### Mine Health Standards Branch

- Compiles and analyzes the results of research, studies, and investigations pertaining to selected mine health hazards for preparing criteria and recommended standards.

- Prepares criteria for recommended health standards.

- Assists the Mine Safety and Health Administration, Department of Labor, in the development of draft regulations.

## DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS, AND FIELD STUDIES

### Hazard Evaluation and Technical Assistance Branch

- Conducts the legislatively mandated health hazard evaluation program.

- Provides medical, technical, and consultative assistance to Federal, State, and local agencies, labor, industry, and others to control occupational health hazards and to prevent related trauma and diseases.

### Industrywide Studies Branch

- Conducts epidemiological industrywide field studies to determine the incidence and prevalence of acute and chronic disease in the working population and their offspring.

### Surveillance Branch

- Develops and maintains a national surveillance system for the early detection and continuous assessment of the magnitude and extent of occupational illness, and exposures to hazardous agents.

## DIVISION OF TECHNICAL SERVICES

### Clearinghouse for Occupational Safety and Health Information

- Receives, stores, retrieves, and disseminates technical information on occupational safety and health hazards.

Technical Information Development Branch

- Prepares and annually revises the legislatively mandated Registry of Toxic Effects of Chemical Substances.
- Develops publications promoting safe and healthful working conditions.

DIVISION OF BIOMEDICAL AND BEHAVIORAL SCIENCE

- Conducts laboratory research for the development of criteria for standards in the areas of toxicology, behavioral science, physiology, ergonomics, and the effects of physical agents.

Experimental Toxicology Branch

- Performs laboratory research to develop critical toxicity data on materials found in the occupational environment.
- Investigates the mechanisms of occupational disease.
- Contributes to the development of occupational health criteria for the recommmendation of standards.

DIVISION OF PHYSICAL SCIENCES AND ENGINEERING

Control Technology Research Branch

- Plans and conducts laboratory and worksite research to assess and develop engineering control techniques and personal protective equipment to prevent worker exposure to toxic substances and harmful physical agents.

DIVISION OF RESPIRATORY DISEASE STUDIES

- Conducts clinical and epidemiological research on occupational respiratory disease.
- Provides legislatively mandated medical and autopsy services under the Federal Mine Safety and Health Act of 1977.
- Conducts medical research to fulfill the Institute's responsibilities under the Federal Mine Safety and Health Act of 1977.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop** |
|---|---|---|
| Office of the Director | 301-443-1530 | Rockville, MD |
| Office of Administrative and Management Services | 301-443-1697 | Rockville, MD |
| Office of Program Planning and Evaluation | 301-443-4364 | Rockville, MD |
| Office of Extramural Coordination and Special Projects | 301-443-6437 | Rockville, MD |
| Division of Criteria Documentation and Standards Development | 301-443-3680 | Rockville, MD |
| Division of Surveillance, Hazard Evaluations, and Field Studies | 513-684-2427 | Cincinnati, OH |
| Division of Technical Services | 513-684-8302 | Cincinnati, OH |
| Division of Biomedical and Behavioral Science | 513-684-8465 | Cincinnati, OH |
| Division of Physical Sciences and Engineering | 513-684-4321 | Cincinnati, OH |
| Division of Respiratory Disease Studies | 304-599-7474 | Morgantown, WV |
| Public Information Officer | 301-443-2140 | Rockville, MD |
| Legislative Officer | 301-443-2140 | Rockville, MD |
| Clearinghouse for Occupational Safety and Health Information | 513-684-8326 | Cincinnati, OH |

REGIONAL AND FIELD OFFICES

| Name | Address | Phone |
|---|---|---|
| NIOSH<br>DHEW, Region I | Government Center<br>(JFK Fed. Bldg.)<br>Boston, MA 02203 | 617-223-6668<br>FTS: 223-6668 |

*FTS numbers are the same.

**For the complete address see the first page of this section.

| Name | Address | Phone |
|---|---|---|
| NIOSH<br>DHEW, Region II | Federal Bldg.<br>26 Federal Plaza<br>New York, NY 10007 | 212-264-2485<br>FTS: 264-2485 |
| NIOSH<br>DHEW, Region III | P.O. Box 13716<br>Philadelphia, PA 19101 | 215-596-6716<br>FTS: 596-6716 |
| NIOSH<br>DHEW, Region IV | 101 Marietta Tower<br>Suite 502<br>Atlanta, GA 30303 | 404-221-2396<br>FTS: 242-2313 |
| NIOSH<br>DHEW, Region V | 300 South Wacker Drive<br>33rd Floor<br>Chicago, IL 60606 | 312-886-3881<br>FTS: 353-3881 |
| NIOSH<br>DHEW, Region VI | 1200 Main Tower Bldg.<br>Room 1700-A<br>Dallas, TX 75202 | 214-767-3916<br>FTS: 729-3916 |
| NIOSH<br>DHEW, Region VII | 601 East 12th Street<br>Kansas City, MO 64106 | 816-374-5332<br>FTS: 758-5332 |
| NIOSH<br>DHEW, Region VIII | 11037 Federal Building<br>Denver, CO 80294 | 303-837-3979<br>FTS: 327-3979 |
| NIOSH<br>DHEW, Region IX | 50 United Nations Plaza<br>San Francisco, CA 94102 | 415-556-3781<br>FTS: 556-3781 |
| NIOSH<br>DHEW, Region X | 1321 Second Avenue<br>(Arcade Bldg.)<br>Seattle, WA 98101 | 206-442-0530<br>FTS: 399-0530 |

# STATUTORY AUTHORITIES*

## Occupational Safety and Health Act of 1970

### Public Law 91-596 29 U.S.C. § 651

For a brief history of this Act, please refer to the section on the Occupational Safety and Health Administration, page __.

**Key Sections of Act--Toxics Focus**

| | |
|---|---|
| sec. 20(a)(2) | Authorizes the Secretary of Health, Education, and Welfare (HEW) (as of May 4, 1980--Department of Health and Human Services (DHHS)) to undertake various types of research relating to toxic substances in the work environment in order to meet his responsibility for the formulation of health and safety standards under this Act. |
| sec. 20(a)(5) | Allows the Secretary of HEW (now DHHS) to develop regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which may endanger the health or safety of employees. |
| sec. 20(a)(6) | Directs the Secretary of HEW (now DHHS) to provide annually a "list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur."<br>Authorizes the Secretary to perform workplace evaluations with regard to the toxic effect of concentrations found there. (Health Hazard Evaluations) |
| sec. 20(a)(e) | Delegates the functions of the Secretary of HEW (now DHHS) under this Act to the Director of NIOSH. |
| sec. 21 | Directs the Secretary of HEW (now DHHS) to conduct education and training programs to ensure an adequate supply of personnel to carry out this Act. |
| sec. 22(a) | Establishes NIOSH within HEW (now DHHS) to perform the Secretary of HEW's functions under sections 20 and 21 of this Act. |

sec. 22(c) Authorizes NIOSH to develop and recommend occupational safety and health standards and to perform all functions of the Secretary of HEW (now DHHS) under sections 20 and 21 of this Act.

## Federal Mine Safety and Health Amendments Act of 1977

## Public Law 95-164 30 U.S.C. § 802

The Federal Mine Safety and Health Amendments Act of 1977 was signed by President Carter on November 9, 1977.

The law is the first to bring all mines in the U.S.--more than 20,000 underground and surface, coal and noncoal facilities--under a single safety and health program. It is also the first safety and health program to cover all of the Nation's 400,000 miners.

The Act repeals the Federal Metal and Nonmetallic Mine Safety Act of 1966 and embodies many aspects of the Coal Mine Health and Safety Act of 1969, adding strengthening provisions and expanding its scope to cover all mines.

On March 9, 1978, (120 days after enactment) responsibility for enforcing and administering mine safety and health was transferred from the U.S. Department of the Interior to the U.S. Department of Labor. The Act created a new Mine Safety and Health Administration headed by an assistant secretary of labor.

The law also established an independent, five-member Federal Mine Safety and Health Review Commission to decide on appeals of enforcement of actions by mine operators or representatives of miners.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 101(a)(6)(b) | Stipulates that for each toxic material or harmful agent found in a mine, NIOSH must determine potential toxicity at concentrations used or found in the mine. |
| sec. 103(a) | Authorizes NIOSH to make inspections in mines to obtain information on health and safety conditions and mandatory standards. |
| sec. 501(a) | Authorizes NIOSH to engage in research activities relating to mine safety and health. |

# TOXICS-RELATED ACTIVITIES*

Current programs within NIOSH are divided into four major areas: research, criteria documentation and standards development, technical assistance, and manpower development. Summaries of the first three areas will be included in this section.

## Research

The largest effort within NIOSH, both in terms of dollars and personnel, is directed toward applied occupational health and safety research. Most of the research is concerned with developing new or modifying existing criteria for recommended occupational health and safety standards. Primary areas of research are toxicology, physical and chemical agents, physiology and ergonomics, engineering, behavioral and motivational factors, and epidemiological industrywide studies. Several of these areas are highlighted below.

A major objective of the toxicology research is to determine acute, subchronic, and chronic toxicities of new or existing industrial chemicals in the workplace. These data, besides being used for the development of criteria documents, are also utilized to calculate a relative hazard index for each material tested and to identify the most dangerous routes of exposure.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have been inadvertently omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

NIOSH's Industrywide Studies Program develops basic information to be included in the development of recommended standards. The objectives of this program are: to determine the health experience of current or former workers; to evaluate the industrial environment in terms of stressful agents present, degree of exposure, sources of contaminants, and present controls; to develop to the extent possible, an exposure-response relationship between each agent or combination of agents and incidence of specific diseases; to devise medical examination procedures which will detect in employees the effects of exposures to harmful agents; and to formulate sampling methods and environmental survey strategies.

These research efforts are undertaken at the NIOSH research labs (located in Cincinnati, Ohio, and Morgantown, West Virginia) and under contract with universities and private research institutes.

## Criteria Documentation and Standards Development

Criteria Documents. NIOSH provides recommended health and safety standards in the form of criteria documents to the Secretary of Labor for promulgation and enforcement. Criteria documents are publications on specific occupational health and safety problems. The development of criteria documents includes not only the recommendation of the environmental limit where information is available to support it, but also the recommendation of work practice controls, medical evaluation, information for the workers to recognize and avoid the hazard, and identification of specific research gaps identified during the development of the criteria document.

Subjects may include individual chemicals or physical agents, classes or groups of chemicals or agents, industries, occupations, or specific processes within an industry. The order of hazards selected for criteria development is determined by a NIOSH priority system based on the number of workers exposed; severity of the toxic response including carcinogenicity; amount of material being used, produced, or handled; and new information regarding occupational health hazards.

The criteria documents are prepared by the Division of Criteria Documentation and Standards Development located at NIOSH headquarters in Rockville, Maryland.

Special Hazard Reviews. The complex and time-consuming criteria documentation process is not always appropriate for particularly hazardous substances, including some carcinogens. For these hazards, NIOSH developed a Special Hazard Review which contains information on the hazard's known health effects, recommended good work practices and exposure levels, suggested monitoring and recordkeeping requirements, and sampling methods.

Emergency Temporary Standards. Where NIOSH determines that worker health protection requires immediate action, a recommended emergency temporary standard is developed and sent to OSHA. The preparation of an emergency temporary standard may be initiated as a result of OSHA's compliance experience or because of a report of adverse health reports from industry, research groups, or other interested parties. Information obtained as a result of NIOSH field studies or a health hazard evaluation report can also result in the development of emergency temporary standards.

## Technical Services

NIOSH provides a number of technical services to employees and employers and organizations in the occupational safety and health field. These include:

- Health Hazard Evaluations. A Health Hazard Evaluation is an on-site investigation of health hazards in a specific workplace. The evaluations may be requested by an authorized representative of employees or by an employer. If a NIOSH investigator finds any employee in imminent danger, his employer and the Department of Labor are notified immediately. In cases where there is no imminent danger, NIOSH will mail a copy of the findings to the employer or employee who requested the evaluation. NIOSH was also given authority to perform evaluations in mines under the Federal Mine Safety and Health Act of 1977.

- Current Intelligence Bulletins. The Bulletins serve as a means to promptly notify persons in the occupational field of health and safety hazards that may not have been previously recognized. The Bulletin is based on the evaluation of new information on a particular hazard in light of other known epidemiology, production, and use data. Since accuracy and speed are of the utmost importance, the review and evaluation process preceding issuance takes only 3 to 4 weeks.

- Registry of Toxic Effects of Chemical Substances. Annual publication of the registry is mandated by the OSH Act. The registry itself is a compendium of unevaluated toxicity data abstracted from scientific literature. The format permits searches by groupings of chemicals or by chemical structure. The current edition, (1978) lists over 33,000 different substances, as well as 90,000 synonyms for those substances.

- National Occupational Hazard Survey. This 4-year effort was designed to find out how many workers are exposed to specific hazards, which industries they work in, and the jobs they hold. After visits and contacts with over 5,000 workplaces, NIOSH investigators accumulated data on 4,500 potential hazards in 66 types of industries and 456 occupational groups.

# *DEPARTMENT OF LABOR*

200 Constitution Avenue NW.
Washington, D.C. 20210

Locator: 202-523-6666
Information: 202-523-7304

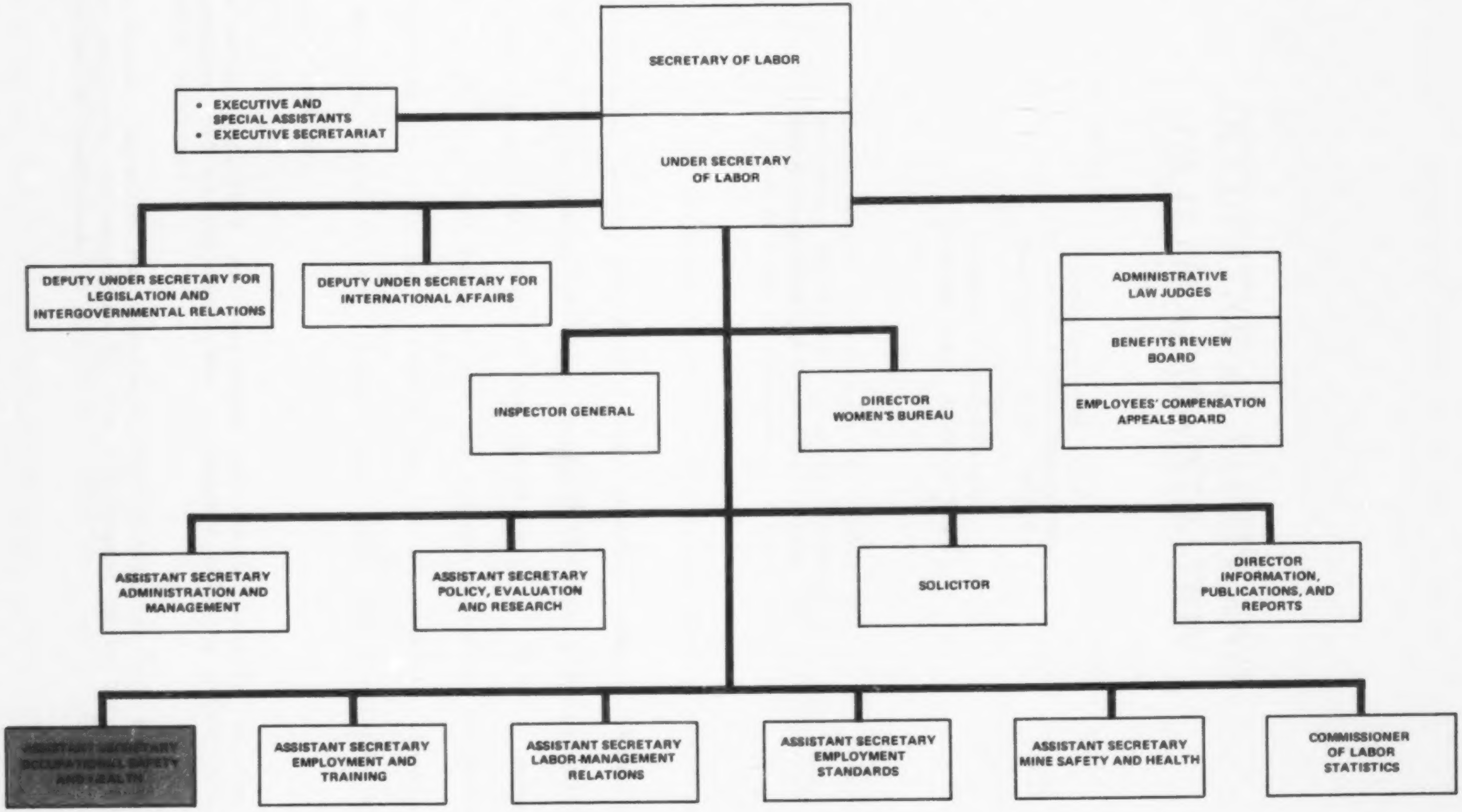
The purpose of the Department of Labor is to foster, promote, and develop the welfare of the wage earners of the United States, to improve their working conditions, and to advance their opportunities for profitable employment. In carrying out this mission, the Department administers more than 130 Federal labor laws guaranteeing workers' rights to safe and healthful working conditions, a minimum hourly wage and overtime pay, freedom from employment discrimination, unemployment insurance, and workers' compensation. The Department also protects workers' pension rights; sponsors job training programs; helps workers find jobs; works to strengthen free collective bargaining; and keeps track of changes in employment, prices, and other national economic measurements. As the Department seeks to assist all Americans who need and want to work, special efforts are made to meet the unique job market problems of older workers, youths, minority group members, women, the handicapped, and other groups.

The Department of Labor, ninth executive department, was created by act approved March 4, 1913. A Bureau of Labor was first created by Congress in 1884 under the Interior Department. The Bureau of Labor later became independent as a Department of Labor without executive rank. It again returned to bureau status in the Department of Commerce and Labor which was created by act of February 14, 1903.

This publication focuses on the duties and activities of the Occupational Safety and Health Administration, which is located under the Assistant Secretary for Occupational Safety and Health.

# DEPARTMENT OF LABOR

## ORGANIZATIONAL CHART*


SECRETARY OF LABOR
UNDER SECRETARY OF LABOR
• EXECUTIVE AND SPECIAL ASSISTANTS
• EXECUTIVE SECRETARIAT
DEPUTY UNDER SECRETARY FOR LEGISLATION AND INTERGOVERNMENTAL RELATIONS
DEPUTY UNDER SECRETARY FOR INTERNATIONAL AFFAIRS
ADMINISTRATIVE LAW JUDGES
BENEFITS REVIEW BOARD
EMPLOYEES' COMPENSATION APPEALS BOARD
INSPECTOR GENERAL
DIRECTOR WOMEN'S BUREAU
ASSISTANT SECRETARY ADMINISTRATION AND MANAGEMENT
ASSISTANT SECRETARY POLICY, EVALUATION AND RESEARCH
SOLICITOR
DIRECTOR INFORMATION, PUBLICATIONS, AND REPORTS
ASSISTANT SECRETARY OCCUPATIONAL SAFETY AND HEALTH
ASSISTANT SECRETARY EMPLOYMENT AND TRAINING
ASSISTANT SECRETARY LABOR-MANAGEMENT RELATIONS
ASSISTANT SECRETARY EMPLOYMENT STANDARDS
ASSISTANT SECRETARY MINE SAFETY AND HEALTH
COMMISSIONER OF LABOR STATISTICS

***NOTE:** A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Department of Labor
200 Constitution Avenue NW.
Washington, D.C. 20210

Locator: 202-523-6666
Information: 202-523-8151

Organization....................Page 156
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The Occupational Safety and Health Administration (OSHA) is the agency within the U.S. Department of Labor responsible for administering and enforcing the Occupational Safety and Health Act of 1970. Under the provisions of the Act, OSHA is to develop and enforce mandatory job safety and health standards in order to "...assure as far as possible [that] every working man and woman in the Nation [has] safe and healthful working conditions..." and to:

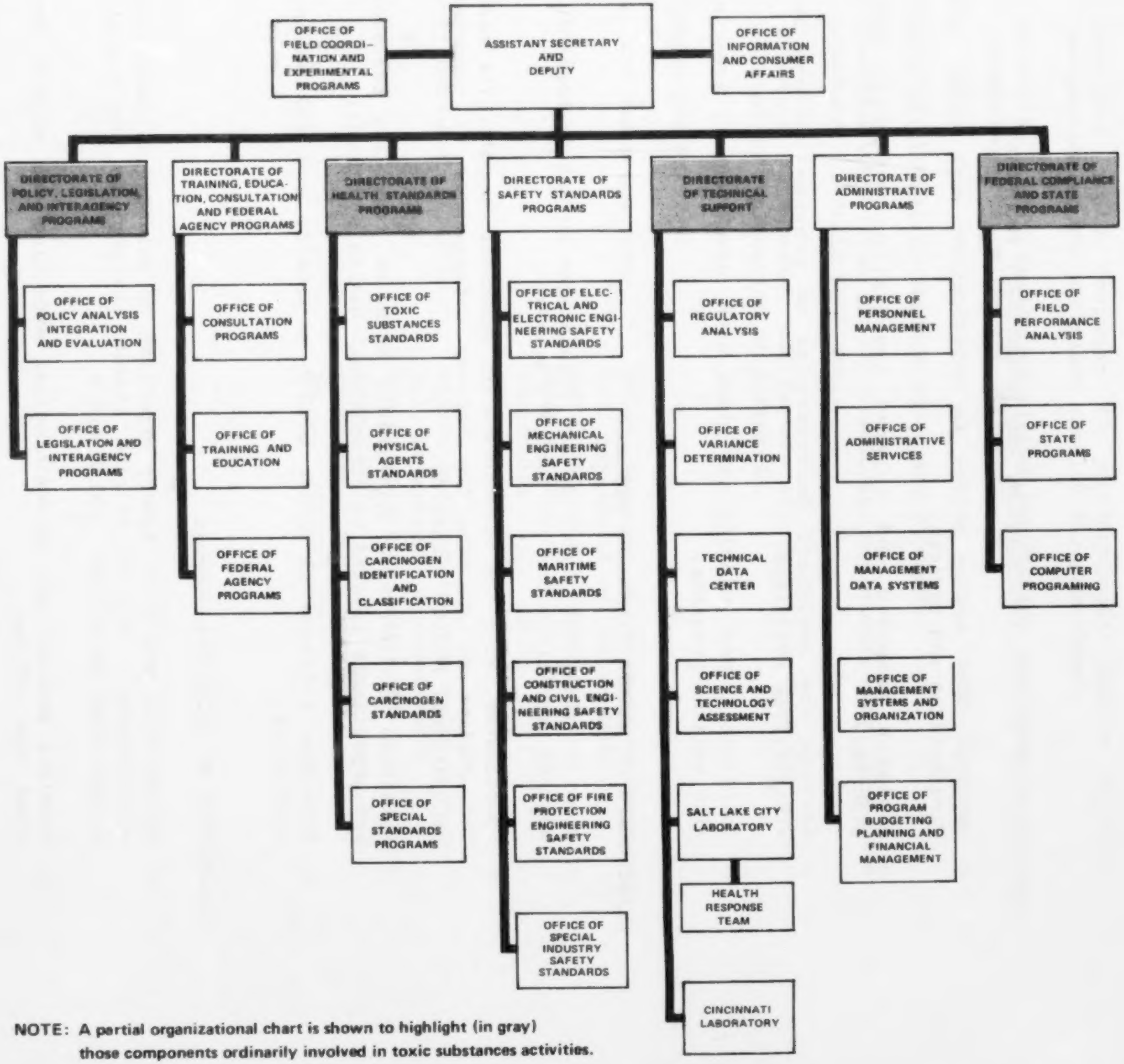
- Encourage employers and employees to reduce hazards in the workplace and to implement new or improve existing safety and health programs.
- Establish "separate but dependent responsibilities and rights" for employers and employees for the achievement of better safety and health conditions.

- Establish reporting and recordkeeping procedures to monitor job-related injuries and illnesses.
- Encourage the development of "fully effective" job safety and health programs by the States. These programs' standards must be at least as effective as those of the Federal program.

## DEPARTMENT OF LABOR

# OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

## ORGANIZATIONAL CHART*


OFFICE OF FIELD COORDINATION AND EXPERIMENTAL PROGRAMS
ASSISTANT SECRETARY AND DEPUTY
OFFICE OF INFORMATION AND CONSUMER AFFAIRS
DIRECTORATE OF POLICY, LEGISLATION, AND INTERAGENCY PROGRAMS
OFFICE OF POLICY ANALYSIS INTEGRATION AND EVALUATION
OFFICE OF LEGISLATION AND INTERAGENCY PROGRAMS
DIRECTORATE OF TRAINING, EDUCATION, CONSULTATION AND FEDERAL AGENCY PROGRAMS
OFFICE OF CONSULTATION PROGRAMS
OFFICE OF TRAINING AND EDUCATION
OFFICE OF FEDERAL AGENCY PROGRAMS
DIRECTORATE OF HEALTH STANDARDS PROGRAMS
OFFICE OF TOXIC SUBSTANCES STANDARDS
OFFICE OF PHYSICAL AGENTS STANDARDS
OFFICE OF CARCINOGEN IDENTIFICATION AND CLASSIFICATION
OFFICE OF CARCINOGEN STANDARDS
OFFICE OF SPECIAL STANDARDS PROGRAMS
DIRECTORATE OF SAFETY STANDARDS PROGRAMS
OFFICE OF ELECTRICAL AND ELECTRONIC ENGINEERING SAFETY STANDARDS
OFFICE OF MECHANICAL ENGINEERING SAFETY STANDARDS
OFFICE OF MARITIME SAFETY STANDARDS
OFFICE OF CONSTRUCTION AND CIVIL ENGINEERING SAFETY STANDARDS
OFFICE OF FIRE PROTECTION ENGINEERING SAFETY STANDARDS
OFFICE OF SPECIAL INDUSTRY SAFETY STANDARDS
DIRECTORATE OF TECHNICAL SUPPORT
OFFICE OF REGULATORY ANALYSIS
OFFICE OF VARIANCE DETERMINATION
TECHNICAL DATA CENTER
OFFICE OF SCIENCE AND TECHNOLOGY ASSESSMENT
SALT LAKE CITY LABORATORY
HEALTH RESPONSE TEAM
CINCINNATI LABORATORY
DIRECTORATE OF ADMINISTRATIVE PROGRAMS
OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF ADMINISTRATIVE SERVICES
OFFICE OF MANAGEMENT DATA SYSTEMS
OFFICE OF MANAGEMENT SYSTEMS AND ORGANIZATION
OFFICE OF PROGRAM BUDGETING PLANNING AND FINANCIAL MANAGEMENT
DIRECTORATE OF FEDERAL COMPLIANCE AND STATE PROGRAMS
OFFICE OF FIELD PERFORMANCE ANALYSIS
OFFICE OF STATE PROGRAMS
OFFICE OF COMPUTER PROGRAMING

**NOTE:** A partial organizational chart is shown to highlight (in gray) those components ordinarily involved in toxic substances activities.

# ORGANIZATION*

DIRECTORATE OF POLICY, LEGISLATION, AND INTERAGENCY PROGRAMS

- Develops OSHA agency policy in coordination with other OSHA Directorates and Offices.
- Analyzes proposed and related legislation affecting OSHA programs.
- Advises the Assistant Secretary as to program options and alternatives available.
- Coordinates OSHA policies and plans with other Federal agencies with related programs.

DIRECTORATE OF HEALTH STANDARDS PROGRAMS

- Provides workplace standards and regulations to assure healthful working conditions for the Nation's workers.
- Coordinates, with the Directorate of Technical Support, the need for studies to evaluate the various consequences of proposed occupational health standards.
- Maintains liaison with appropriate agencies regarding research and experiments related to occupational health standards.
- Provides information about health standards and rulemaking activities.

DIRECTORATE OF TECHNICAL SUPPORT

- Serves as a source of Agency expertise on scientific, economic, environmental, and engineering issues involved in the overall occupational safety and health field.
- Provides medical and epidemiological expertise and support for other OSHA offices.
- Processes variances from the OSHA standards.

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*Note: Only those Directorates which deal with toxics or toxics-related issues are developed in this section.

- Provides chemical analyses and instrument calibration to the OSHA compliance officers.

- Operates a clearinghouse of occupational safety and health data (the Technical Data Center).

- Provides rapid response to occupational health related emergencies at the workplace (Health Response Team).

- Maintains public record containing information pertinent to OSHA rulemaking actions (Docket Office).

## DIRECTORATE OF FEDERAL COMPLIANCE AND STATE PROGRAMS

- Provides directives on all standards, explaining compliance with standard for field personnel.

- Explains, interprets, and answers all questions from the public related to application of standards.

## FOR FURTHER INFORMATION:

| | |
|---|---|
| Federal and State Agencies: | Chief, Division of Interagency Programs<br>U.S. Department of Labor--OSHA<br>200 Constitution Avenue NW.<br>Room N3628<br>Washington, D.C. 20210<br>Phone: 202-553-9296 |
| Industry and General Public: | Chief, Division of News Media Service<br>U.S. Department of Labor--OSHA<br>200 Constitution Avenue NW.<br>Room N3637<br>Washington, D.C. 20210<br>Phone: 202-523-8151 |

# STATUTORY AUTHORITIES

## The Occupational Safety and Health Act of 1970

Public Law 91-596 29 U.S.C. § 651 et seq.

The Occupational Safety and Health Act of 1970 was the result of a concerted effort by Congress to pass nationwide job safety legislation. Prior to 1970, Federal authority for occupational safety and health was confined to few acts quite limited in scope (such as the Walsh-Healy Public Contracts Act, which covered workers employed on certain Federal contracts, the McNamara-O'Hara Services Contract Act, the Maritime Safety Act, and the Construction Safety Act). Only a few States had modern laws or sufficient resources to administer and enforce safety and health regulations. Some had no plans at all. Before OSHA, the quality and scope of the regulations as well as the effort directed toward enforcement and compliance varied widely, with many States fearing that strict adherence to standards would be a competitive and economic disadvantage.

The Occupational Safety and Health Act is the first comprehensive Federal legislation in the field of occupational safety and health. In general, the Act covers all employers and their employees in the 50 States, the District of Columbia, Puerto Rico, the Canal Zone, and all other territories under Federal Government jurisdiction.

As defined by the Act, an employer is any "person engaged in a business affecting commerce who has employees, but does not include the United States or any State or political subdivision of a State."

Section 19 of the Act specifically delegates responsibility for Federal employee occupational safety and health to the head of each Federal agency. This responsibility is comparable to that of employers in the private sector. If an agency is found to be neglecting any area of occupational safety and health for its workers, OSHA may provide advice and assistance in resolving problems through its Office of Federal Agency Programs.

At this time, 24 States or jurisdictions operate occupational safety and health plans that cover both State and local government employees. State and local government employees of States without such plans are excluded from the coverage of the Act.

Three new agencies were established by the Act to carry out the main functions of the statute:

- The Occupational Safety and Health Administration within the Department of Labor, which is responsible for carrying out most of the Secretary's responsibilities under the Act.
- The National Institute for Occupational Safety and Health (NIOSH) within the Department of Health, Education, and Welfare (HEW), which is responsible for conducting research in occupational safety and health areas for use by OSHA in the development of health and safety standards.
- An independent Occupational Safety and Health Review Commission to adjudicate enforcement cases, review citations and proposed penalties, establish abatement dates, etc.

In addition to these agencies, the Act established a 12-member National Advisory Committee on Occupational Safety and Health (NACOSH) which meets at least twice a year to advise, consult with, and make recommendations to the Secretary on matters relating to the administration of the Act.

## Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 3 | Defines terms of importance of the Act. |
| sec. 5 | States the duties of each employer or employee. |
| sec. 5(a)(1) | Requires the employer to maintain a workplace that is "free from recognized hazards that are causing or are likely to cause death or serious physical harm to (the) employees." This section may be used to cite hazards for which there is no current OSHA standard. A hazard is "recognized" if it is a condition that is "...(a) of a *common knowledge* or general recognition in the particular industry in which it occurs, and (b) *detectable* (1) by means of the senses (sight, smell, touch, and hearing), or (2) is of such wide, general recognition as a hazard in the industry that even if it is not detectable by means of the senses, there are generally known and accepted tests for its existence which should make its presence known to the employer. For example, excessive concentrations of a toxic substance in the air would be a *recognized hazard* if they could be detected through the use of measuring devices." |
| sec. 6(b) (1-4) | Authorizes the Secretary to promulgate occupational safety or health standards with provisions for public participation in the rulemaking process. |
| sec. 6(b)(5) | Details the development of standards for toxic materials or harmful physical agents. |
| sec. 6(b)(7) | Requires the use of appropriate forms of warning, suitable protective or control equipment, the monitoring of employees' exposure, and medical examinations or tests as may be necessary. |
| sec. 6(c)(1) | Directs the Secretary to provide for an immediate, emergency temporary standard covering employees exposed to grave danger from exposure to toxic substances, physically harmful agents, or new hazards. |
| sec. 8 | Gives the Administration the authority to enter any work area for inspection and investigation (subject to interpretation of *Marshall vs. Barlows, Inc.*, Supreme Court decision). |
| sec. 8(c)(3) | Requires each employer to keep records of exposure to toxic materials and make them available upon request. |
| sec. 9 | Authorizes the issuance of a citation to employers who have violated any rule or standard. |
| sec. 12 | Establishes the Occupational Safety and Health Review Commission which affirms, codifies, or vacates citations or proposed penalties. |
| sec. 13 | Authorizes the Secretary to petition the courts to restrain imminent danger situations. |

| | |
|---|---|
| sec. 16 | Allows the issuance of variances, tolerances, and exemptions to the Act. |
| sec. 17 | Sets the conditions for penalties. |
| sec. 20 (a)(2) | Directs the Secretary of Health, Education, and Welfare (HEW) to develop specific plans for research, demonstrations, and experiments to produce criteria identifying toxic substances. |
| sec. 20 (a)(3) | Directs the Secretary of HEW to develop criteria to describe safe exposure levels for toxic materials and hazardous physical agents. |
| sec. 20 (a)(5) | Allows the Secretary of HEW to develop regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which may endanger the health or safety of employees. |
| sec. 20 (a)(6) | Directs the Secretary of HEW to provide annually a "list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. |
| sec. 22 | Establishes the National Institute for Occupational Safety and Health to develop and recommend standards. |

## Regulatory Options Available Under Statute

- Promulgate occupational safety and health standards
- Authorize inspections and investigations
- Issue citations and proposed penalties
- Petition the courts to restrain imminent danger situations
- Approve or reject State plans for administering and enforcing health/safety programs under the Act

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

1. Decision to initiate health standards development project based on NIOSH recommendations, new research findings, petitions, or court order. An Advisory Committee, permanent or ad hoc, may be convened either to review current data and make recommendations or to review OSHA-generated drafts of proposals (arising from Activity No. 3 below). Advanced Notices of Proposed Rulemaking (ANPRM) may be published in the Federal Register to inform the public of new initiatives.

2. Decision to regulate triggers concurrent analyses, by Project Officer in Health Standards Programs (HSP) and counterparts in Technical Support. The Project Officer reviews all available scientific literature on the hazard as well as relevant enforcement data and existing standards. The Project Officer shares data with Technical Support staff who make initial regulatory analysis, and begin appropriate studies of economic/technological feasibility.

3. Project Officer prepares draft technical standard and preamble. Upon consultation with Technical Support, HSP submits action plan to Secretary of Labor outlining proposed action, need for action, need for regulatory analysis, standard development schedule, etc.

4. Upon approval by the Secretary of Labor, the proposed rule is put into Federal Register format, and a draft environmental impact statement, if required, and draft regulatory analysis, if required, are prepared for publication. Also, if applicable, any studies of economic or technological feasibility are prepared for release to the public.

5. The proposed standard is published in the Federal Register along with information concerning any public hearing(s) to be held on the subject. Other pertinent documents, i.e., draft regulatory analysis, draft environmental impact statement, and any other studies of economic/technological feasibility, are released to the public. A minimum of 60 days is given for receipt of written comments from the public.

6. An informal public hearing is held, if requested by the affected parties, to allow further public comment, questioning of witnesses, and submission of additional data.

7. Project staff (composed of staff from Health Standards, Technical Support, and Solicitor of Labor) analyzes entire rulemaking record to

identify major issues and prepare, if necessary, final environmental impact statement and final regulatory analysis. Major decision points/issues are presented to OSHA management. Review and clearance is obtained from the Assistant Secretary and Secretary.

8. The final standard is published in the Federal Register to become effective in 60-90 days. (Compliance with all parts of a standard may not be required immediately. For example, installation of engineering controls might be given a "phase-in" period of months or even years). If required, the final regulatory analysis and final environmental impact statement are released to the public.

9. If a petition is filed challenging the validity of the final standard, it may be subject to judicial review.

## EXISTING REGULATIONS

| | |
|---|---|
| Occupational Safety and Health Act | 29 CFR 1900-1999 |

# TOXICS-RELATED ACTIVITIES*

## Identification, Classification, and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk

### Directorate of Health Standards

OSHA has published a statement of policy and procedure for the regulation of potential carcinogens found in the occupational environment (January 22, 1980; 45 FR 5002). This action does not in itself impose any requirements on employers but rather establishes a framework for regulatory action by the Agency. The Agency is responding to a need to develop a more expeditious means of evaluating data on potentially carcinogenic materials and for developing regulations to provide adequate employee protection from exposure to these substances.

### Health Standards Development

New and revised mandatory standards are proposed and promulgated to protect the safety and health of workers. Priority needs for safety and health standards are determined for particular occupations, industries, and work environments, or standards development projects are initiated as a result of petitions, research findings, and criteria documents. Public comment is invited on proposed standards. Informal hearings on proposed standards provide for public testimony and submission of additional data. The record of rulemaking is evaluated, and final standards are issued on the basis of substantial evidence in this record. Summaries of some current toxics-related rules under development follow.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have been inadvertently omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

## OCCUPATIONAL EXPOSURE TO BERYLLIUM
## OFFICE OF CARCINOGEN STANDARDS

OSHA is developing a standard for occupational exposure to beryllium. The standard would include permissible exposure limits and provisions for medical surveillance, exposure monitoring, methods of compliance, employee training, recordkeeping, etc.

The Agency is responding to a need to provide more effective protection of employees from the health hazards of beryllium exposure. The potential hazards include berylliosis (a disease of the lungs and other organs) and cancer.

## STANDARDS COMPLETION PROJECT
## OFFICE OF SPECIAL STANDARDS PROGRAMS

The purpose of the project is to establish a general standard on environmental monitoring of worker exposure to toxic chemicals, medical surveillance of exposed employees, employee training, and recordkeeping. In addition, supplementary, substance-specific guidelines would be prepared for employer and employee use. The project covers the current list of chemicals for which OSHA has only permissible exposure limits (29 CFR 1910.1000, Tables Z-1, Z-2, and Z-3). The Occupational Safety and Health Act of 1970 describes the above provisions as important elements of a comprehensive and effective program of industrial hygiene. Conclusion of this project is important to assuring that the intent of the act is fulfilled.

## OCCUPATIONAL EXPOSURE STANDARDS FOR ASBESTOS, 29 CFR 1910.94(a)
## DIRECTORATE OF HEALTH STANDARDS

OSHA is considering revisions to its current asbestos standard. Revisions might include changes to the current permissible exposure limit and provisions for medical surveillance, monitoring, etc. Research on the health hazards of asbestos and concern for the adequacy of the current standard prompted this review. Asbestos has been linked to a large number of cases of occupationally related cancer.

## OCCUPATIONAL EXPOSURE TO CADMIUM
## OFFICE OF CARCINOGEN STANDARDS

OSHA is considering revisions to amend its current permissible exposure limit for cadmium and to add provisions for medical surveillance, exposure monitoring, etc. Research on the health effects of cadmium indicates that the current standard may not be adequately protective. Exposure to cadmium may cause kidney, liver, adrenal, and other systemic damage as well as several types of cancer.

## OCCUPATIONAL EXPOSURE TO NICKEL
## OFFICE OF CARCINOGEN STANDARDS

OSHA is considering revisions to amend its current permissible exposure limit for nickel and to add provisions for medical surveillance, environmental monitoring, etc. The National Institute for Occupational Safety and Health has published a summary of the toxic effects of nickel and recommendations for controlling occupational exposure to this substance. The NIOSH report, called a Criteria Document, indicated that OSHA's current standard for nickel may not be sufficiently protective. Exposure to nickel may increase the risk of lung and nasal cancer and also causes nasal septum perforation and dermatitis.

## OCCUPATIONAL EXPOSURE TO MBOCA
## OFFICE OF CARCINOGEN STANDARDS

OSHA is developing a standard for occupational exposure to MBOCA (4,4 methylene bis (2-chloroaniline)) which may include a permissible exposure limit and provisions for medical surveillance, environmental monitoring, methods of compliance, employee training, etc. An earlier standard for MBOCA was vacated for a procedural reason through judicial action. MBOCA has been shown to be a carcinogen in three mammalian species.

## CHEMICAL HAZARD IDENTIFICATION
## OFFICE OF SPECIAL STANDARDS PROGRAMS

OSHA is developing a proposal to require employers to inform employees of the identities and hazards of chemicals in the workplace, by means of labels, placards, lists, and substance data sheets. Employees' awareness of the chemical hazards to which they are exposed provides the knowledge necessary for individuals to participate actively in the reduction or elimination of exposure to these harmful agents.

## OCCUPATIONAL EXPOSURE TO HEXAVALENT CHROMIUM
## OFFICE OF CARCINOGEN STANDARDS

OSHA is developing a standard for occupations exposure to hexavalent chromium. The standard would include permissible exposure limits and provisions for medical surveillance, exposure monitoring, methods of compliance, employee training, etc. The Agency is responding to a need to provide more effective protection of employees from the health hazards of hexavalent chromium exposure. The potential hazards include skin ulceration, nasal septum perforation, and cancer.

## OCCUPATIONAL EXPOSURE TO PESTICIDES
## OFFICE OF SPECIAL STANDARDS PROGRAMS

OSHA is developing a generic standard to control occupational exposure to pesticides during the manufacturing and formulating processes. OSHA has determined that employees in the pesticide industry have an increased risk of illness due to their exposure to pesticides, and the Agency has developed several alternative standards designed to reduce this risk. The standards include provisions relating to work practices, medical surveillance, employee training, and respiratory protection.

# DEPARTMENT OF TRANSPORTATION

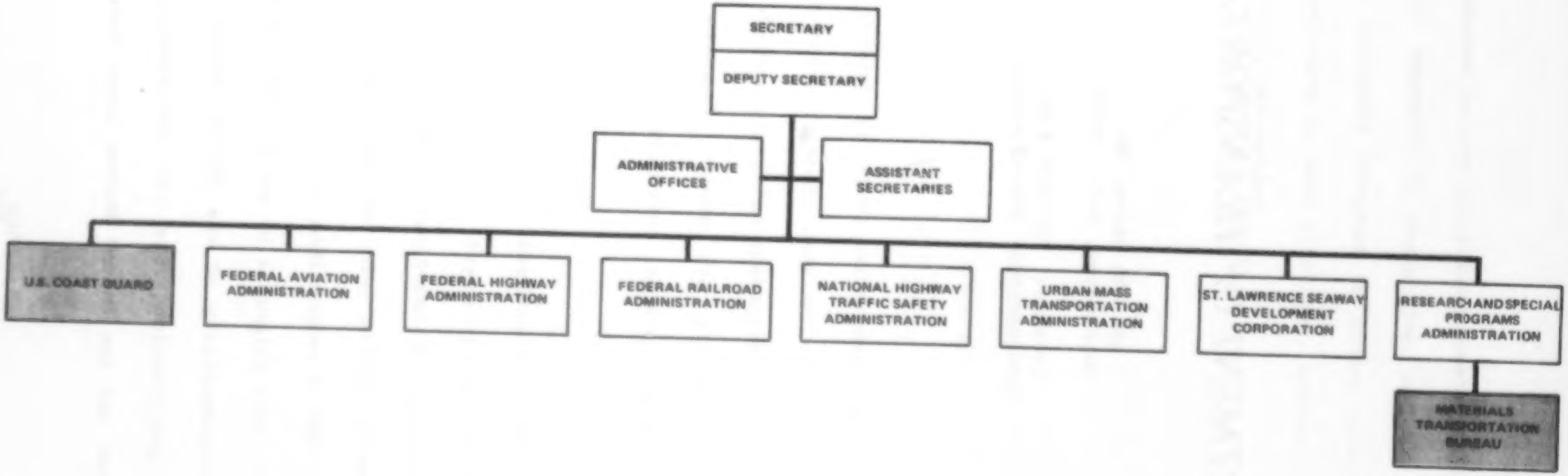
400 7th Street SW.
Washington, D.C. 20590

Locator: 202-426-4000
Information: 202-426-4000

The Department of Transportation (DOT) is responsible for issuing and enforcing regulations ensuring the safe transportation of hazardous materials by all modes of transport. Hazardous materials include, but are not limited to, articles used in industry and general commerce such as explosives, flammable gases and liquids, poisons, corrosives and radioactive materials, as well as other toxic substances.

There are two administrations within the Department which have responsibility for the development of regulations and other activities relating to transportation of hazardous materials. The lead agency is the Materials Transportation Bureau (MTB) of DOT's Research and Special Programs Administration. The MTB is responsible for regulations governing all modes of transportation except bulk shipments by water. Regulations for bulk shipments by water are the responsibility of the United States Coast Guard. For the purposes of this publication, the two administrations--the Materials Transportation Bureau and the United States Coast Guard--will be covered in separate sections.

# DEPARTMENT OF TRANSPORTATION
## ORGANIZATIONAL CHART*


SECRETARY
DEPUTY SECRETARY
ADMINISTRATIVE OFFICES
ASSISTANT SECRETARIES
U.S. COAST GUARD
FEDERAL AVIATION ADMINISTRATION
FEDERAL HIGHWAY ADMINISTRATION
FEDERAL RAILROAD ADMINISTRATION
NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION
URBAN MASS TRANSPORTATION ADMINISTRATION
ST. LAWRENCE SEAWAY DEVELOPMENT CORPORATION
RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
MATERIALS TRANSPORTATION BUREAU

*NOTE: Only a partial organizational chart is shown to highlight (in gray) the two administrations within the Department which are involved in toxics-related activities.

# MATERIALS TRANSPORTATION BUREAU

Research and Special Programs Administration
Department of Transportation
400 7th Street SW.
Washington, D.C. 20590

Locator: 202-426-4000
Information: 202-426-2301

Organization....................page 174
Statutory Authority.............page 177
Regulatory Development..........page 179
Toxics-Related Activities.......page 180

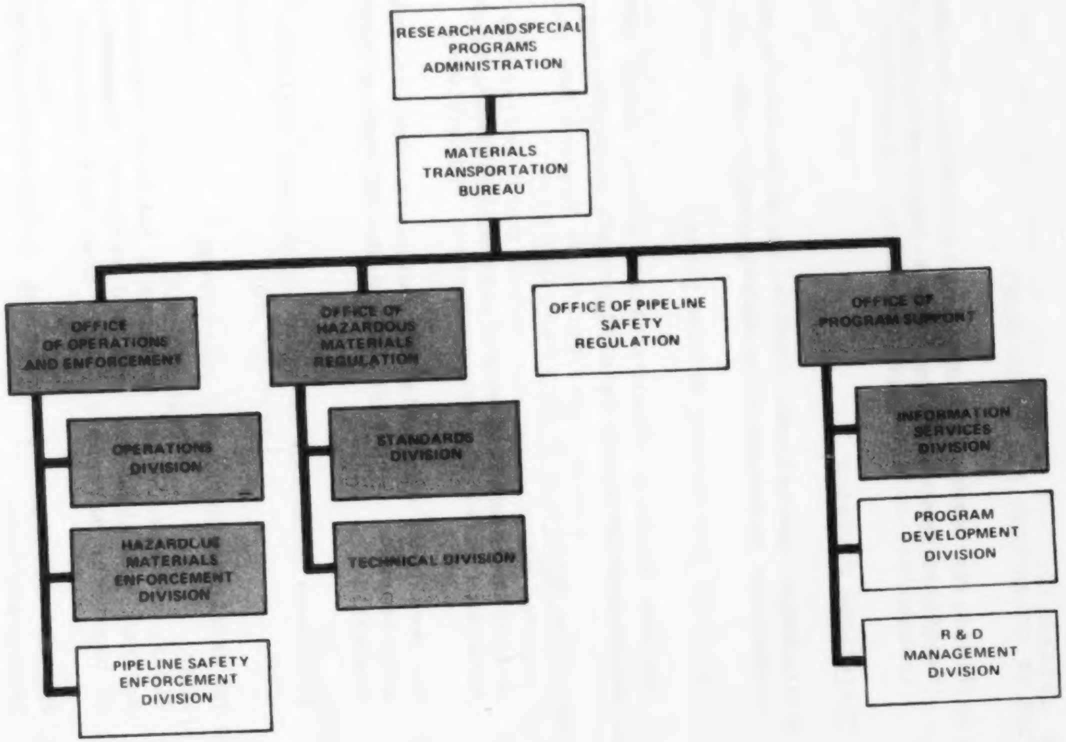
In 1974, Congress enacted the Hazardous Materials Transportation Act which delegated broad authority to the Secretary of Transportation in all matters concerning the transportation of hazardous materials. In July 1975, the Secretary began to make the administrative changes that Congress authorized in the Act. By secretarial order, he created the Materials Transportation Bureau (MTB) and made it the lead agency in the Department of Transportation's (DOT) hazardous materials transportation safety program.

In the order creating the Bureau, the Secretary delegated to the Director of MTB the authority to issue all hazardous materials safety regulations except those relating to bulk transportation by water. (The U.S. Coast Guard, discussed in the next section, is responsible for all regulations and activities relating to bulk transportation by water.) To ensure Departmentwide coordination under the new structure, the Director of MTB must consult with the other modal administrators within DOT (Federal Highway Administration [FHA], Federal Aviation Administration [FAA], Federal Railroad Administration [FRA]) before issuing regulations on matters affecting them.

In addition, with the responsibility for enforcement of regulations other than those applicable to an individual mode of transportation, the MTB places primary emphasis on compliance and enforcement authority over container manufacturers and multimodal reconditioners and shippers of hazardous materials. The other operating administrators retain jurisdictional responsibility for enforcement and compliance actions relating to unimodal transportation of hazardous materials.

# U.S. DEPARTMENT OF TRANSPORTATION
# RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
# MATERIALS TRANSPORTATION BUREAU

## ORGANIZATIONAL CHART*


RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
MATERIALS TRANSPORTATION BUREAU
OFFICE OF OPERATIONS AND ENFORCEMENT
OFFICE OF HAZARDOUS MATERIALS REGULATION
OFFICE OF PIPELINE SAFETY REGULATION
OFFICE OF PROGRAM SUPPORT
OPERATIONS DIVISION
HAZARDOUS MATERIALS ENFORCEMENT DIVISION
PIPELINE SAFETY ENFORCEMENT DIVISION
STANDARDS DIVISION
TECHNICAL DIVISION
INFORMATION SERVICES DIVISION
PROGRAM DEVELOPMENT DIVISION
R & D MANAGEMENT DIVISION

***NOTE:** Only a partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

# ORGANIZATION*

## OFFICE OF OPERATIONS AND ENFORCEMENT

- Plans and performs inspections, testing, registration, and enforcement functions necessary to assume compliance with MTB hazardous materials transportation and pipeline safety regulations.

### Operations Division

- Conducts operational studies to help assure enforcement of hazardous materials transportation safety regulations.
- Develops enforcement action plans.
- Reviews National Transportation Safety Board (NTSB) reports and safety recommendations and determines DOT response.

### Hazardous Materials Enforcement Division

- Conducts inspections and investigations to ensure enforcement of hazardous materials transportation regulations.
- Reviews and responds to requests for inconsistency rulings and nonpreemption determinations (in conjunction with the Office of Chief Counsel).
- Processes hazardous material compliance actions.

## OFFICE OF HAZARDOUS MATERIALS REGULATION

- Plans, recommends and develops a national regulatory program to protect against the risks to life and property inherent in the transportation of hazardous materials (other than bulk transport by water).
- Issues Notices of Proposed Rulemaking (NPRM), exemptions, and interpretations.

### Standards Division

- Prepares hazardous materials transportation regulations for issuance or revision.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Evaluates applications for exemptions.
- Maintains liaison with other Federal agencies and other organizations concerning hazardous materials standards.

### Technical Division

- Provides technical evaluations of petitions for rulemaking and exemptions.
- Prepares technical reports on specific aspects related to the development of hazardous materials transportation regulations.

## OFFICE OF PROGRAM SUPPORT

- Provides administrative and research and development support for MTB hazardous materials and pipeline safety regulatory, compliance, and enforcement programs.

### Information Services Division

- Develops and conducts training and public programs for dissemination of safety information and Federal standards requirements.
- Establishes and maintains an MTB docket and information service for all hazardous materials and pipeline safety official matters.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Office of the Director | 202-755-9260 | DMT-1 |
| Office of Operations and Enforcement | 202-755-9247 | DMT-10 |
| Operations Division | | |
| Hazardous Materials Enforcement Division | 202-755-5894 | DMT-12 |

*FTS numbers are the same

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Office of Hazardous Materials Regulation | 202-426-0656 | DMT-20 |
| Standards Division | 202-426-2075 | DMT-21 |
| Technical Division | 202-755-4906 | DMT-22 |
| Office of Program Support | 202-472-0656 | DMT-40 |
| Information Services Division | 202-472-2784 | DMT-43 |

# STATUTORY AUTHORITIES

## Hazardous Materials Transportation Act

### Public Law 93-633   49 U.S.C. § 1801

The Hazardous Materials Transportation Act (HMTA) was developed because of the many problems that had been encountered in the administration of other statutes concerning the transportation of hazardous materials (Dangerous Cargo Act, Transportation of Explosives Act, Federal Aviation Act, Federal Railroad Safety Act).

The goal of HMTA is to "improve the regulatory and enforcement authority of the Secretary of Transportation to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce."

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 103 | Defines "hazardous materials." |
| sec. 104 | Authorizes the Secretary to designate materials as hazardous when the transportation of a particular quantity and form of a material may pose an "unreasonable risk" to health, safety, or property. |
| sec. 105 | Requires the Secretary to develop regulations that govern any safety aspect of the transportation of hazardous materials. |
| sec. 106 | Authorizes the Secretary to establish criteria for handling hazardous materials. |
| sec. 107 | Provides for exemptions and exclusions from the Act. |
| sec. 111 | Allows the Secretary to petition the courts for the suspension or restriction of the transportation of a hazardous material which poses an "imminent hazard." |

| | |
|---|---|
| sec. 112 | Preempts State and local requirements that are inconsistent with the Act or any regulation issued under the Act. |

Regulatory Options Available Under Statute

- o Can require special packaging, handling, labeling, placarding, routing, or other actions necessary to ensure the safe transportation of hazardous materials
- o Can petition the courts to suspend or restrict the transportation of hazardous material which poses an imminent hazard

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

1. A petition to issue, amend, or repeal a regulation is received or is proposed as a result of internal action.

2. All activity regarding the proposed rule must be coordinated with the modal administration affected by the rule (Federal Highway Administration (FHA), Federal Aviation Administration (FAA), Federal Railroad Administration (FRA).

3. Depending on the complexity of the rule, the Bureau may publish an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register. Otherwise, a Notice of Proposed Rulemaking is published and comments are solicited.

4. All comments received as well as the recommendations of any technical advisory group established for the purpose of reviewing the rule are considered.

5. The Director may initiate any further rulemaking proceedings that he deems necessary.

6. The final rule is prepared, reviewed by the General Counsel (Research and Special Programs Administration) and then submitted to the Director for his consideration.

7. If the Director adopts the regulation, it is published in the Federal Register.

## EXISTING REGULATIONS

| | |
|---|---|
| Hazardous Materials Transportation Act | |
| Hazardous Materials Regulations | 49 CFR 171-179 (Subchapter C) |
| Procedural Regulations | 49 CFR 106-107 |

# TOXICS-RELATED ACTIVITIES *

## Compliance Enforcement Program

The Department's Compliance Enforcement Program has two main objectives: (1) to reduce the number of transportation incidents, and (2) to minimize the risk of catastrophic occurrences resulting from the violation of hazardous materials regulations. Each modal administration (FAA, FHA, FRA, U.S. Coast Guard) retains inspection and enforcement authority over its modal carriers, while the MTB provides guidance and technical support to ensure uniformity in the interpretation and application of the regulation.

## Research and Development Program

The Department utilizes the services of a number of Federal and private research organizations to supply the technical data needed to support the development, modification, compliance, and enforcement of hazardous materials regulations. In 1978 the MTB completed and made available to the public a comprehensive emergency response training program for the safe handling of hazardous materials.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

# *UNITED STATES COAST GUARD*

2100 Second Street SW.
Washington, D.C. 20593

Locator: 202-426-4000
Information: 202-426-2158

Organization..................page 183
Statutory Authority...........page 188
Regulatory Development........page 190
Toxics-Related Activities.....page 191

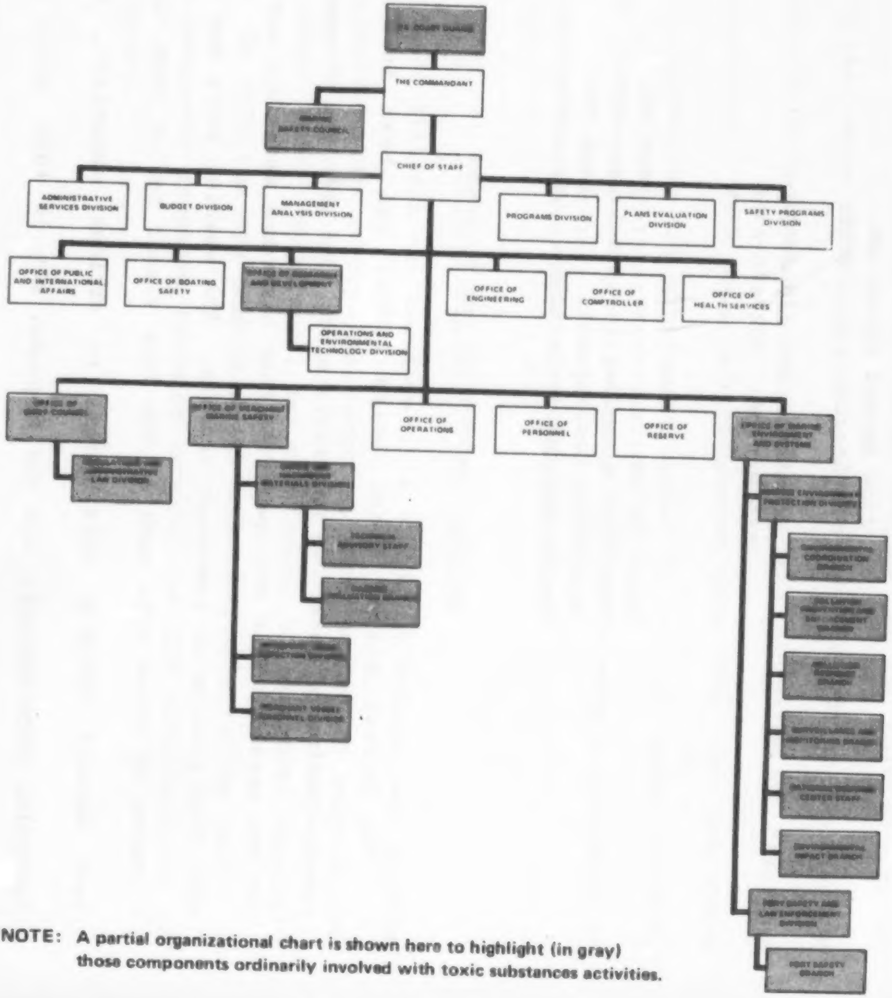
The United States Coast Guard (USCG) has been involved with the transportation of hazardous materials since 1852 when the Steamship Inspection Act was passed. This Act specified that hazardous materials were to be stowed away from boilers on passenger vessels. The ensuing years saw the passage of a number of other Acts such as the Tank Vessel Act of 1936, which subjected tank vessels carrying bulk cargos to various inspection, licensing, and operating requirements; and the Magnuson Act of 1950, which gave the Coast Guard broad authority regarding the supervision of cargo loading and storing, inspection of vessels, and control of ship movements.

The pollution prevention role of the 1936 Tanker Act was expanded with the passage of the Ports and Waterways Safety Act of 1972 as amended by the Port and Tanker Safety Act of 1978. This Act was designed to promote the safety of ports,, harbors, waterfront areas, and navigable waters of the United States.

# U.S. DEPARTMENT OF TRANSPORTATION

# UNITED STATES COAST GUARD

## ORGANIZATIONAL CHART*


U.S. COAST GUARD
THE COMMANDANT
MARINE SAFETY COUNCIL
CHIEF OF STAFF
ADMINISTRATIVE SERVICES DIVISION
BUDGET DIVISION
MANAGEMENT ANALYSIS DIVISION
PROGRAMS DIVISION
PLANS EVALUATION DIVISION
SAFETY PROGRAMS DIVISION
OFFICE OF PUBLIC AND INTERNATIONAL AFFAIRS
OFFICE OF BOATING SAFETY
OFFICE OF RESEARCH AND DEVELOPMENT
OPERATIONS AND ENVIRONMENTAL TECHNOLOGY DIVISION
OFFICE OF ENGINEERING
OFFICE OF COMPTROLLER
OFFICE OF HEALTH SERVICES
OFFICE OF CHIEF COUNSEL
LAW DIVISION
OFFICE OF MERCHANT MARINE SAFETY
MATERIALS DIVISION
TECHNICAL ADVISORY STAFF
OFFICE OF OPERATIONS
OFFICE OF PERSONNEL
OFFICE OF RESERVE
OFFICE OF MARINE ENVIRONMENT AND SYSTEMS
MARINE ENVIRONMENTAL PROTECTION DIVISION
COORDINATION BRANCH
BRANCH
CENTER STAFF
IMPACT BRANCH
PORT SAFETY AND LAW ENFORCEMENT DIVISION
PORT SAFETY BRANCH

*NOTE: A partial organizational chart is shown here to highlight (in gray) those components ordinarily involved with toxic substances activities.

# ORGANIZATION*

## MARINE SAFETY COUNCIL (G-CMC)

- Manages and monitors the Coast Guard's program for the development and implementation of regulations affecting the public including those related to toxic substances.
- Is composed of seven members--The Chief Counsel, and the Chiefs of the Offices of Merchant Marine Safety, Operations, Engineering, Boating Safety, Marine Environment and Systems, and Public and International Affairs.

## OFFICE OF RESEARCH AND DEVELOPMENT (G-D)

- Plans, directs, and coordinates a program of research, development, testing, and evaluation for the Coast Guard aimed at improving or devising new techniques, methods, equipment, etc.
- Conducts a program to develop equipment and methods for responding to discharges of hazardous chemicals into waters of the United States.
- Develops and maintains the Chemical Hazards Response Information System.

## OFFICE OF CHIEF COUNSEL (G-L)

- Renders advisory services, opinions, and decisions on all matters of a legal nature.
- Serves as Chairman of the Marine Safety Counsel.

### Regulations and Administrative Law Division (G-LRA)

- Is responsible (under the direction of the Chief Counsel) for the legal sufficiency of the Coast Guard's public rules and other regulatory matters.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Reviews rules and regulations for their application to the Coast Guard.

## OFFICE OF MERCHANT MARINE SAFETY (G-M)

- Oversees the program for prevention of marine casualties.
- Responsible for the inspection of merchant vessels for compliance to safety standards.

### Cargo and Hazardous Materials Division (G-MHM)

- Initiates or reviews regulations relating to hazardous cargo containment and handling.
- Studies data on toxicity and other hazards to determine the safety precautions necessary when handling dangerous cargo.
- Identifies and monitors research projects in hazardous material safety.
- Maintains liaison with other Federal agencies and represents the Coast Guard on advisory committees involved in regulating hazardous material and dangerous cargo.
- Administers a program for certification of foreign chemical and gas tanker vessels.

#### Technical Advisory Staff (G-MHM)

- Initiates and provides technical management for research and development projects on hazardous materials.
- Directs activities of the NAS-USCG Advisory Committee on Hazardous Materials.
- Acts as a liaison with the Natural Research Council Advisory Center on Toxicology.

#### Hazard Evaluation Branch (G-MHM-3)

- Conducts the hazard analysis of chemicals prior to authorization for shipment.
- Initiates research to assign toxicity, fire, and reactivity hazards to chemicals being or likely to be carried by water.
- Reviews toxicological data from a variety of sources for possible incorporation into Coast Guard regulations.

### Merchant Vessel Inspection Division (G-MUI)

- Develops and enforces safety standards for vessels.

- Issues standards for the protection of merchant seamen from exposure to chemicals.

Merchant Vessel Personnel Division (G-MVP)

- Establishes standards for licensing of U.S. merchant seamen and levels of staffing for U.S. vessels.

- Is currently upgrading the qualifications for tankerman endorsement to more fully address transfer operations of hazardous materials.

## OFFICE OF MARINE ENVIRONMENT AND SYSTEMS (G-W)

- Administers a coordinated Coast Guard environmental program.

- Manages a comprehensive ports and waterways system encompassing all aspects of marine transportation except vessel safety.

Marine Environmental Protection Division (G-WEP)

- Plans, coordinates, implements, and monitors a program to prevent, detect, and control pollution of the marine environment in accordance with statutory requirements and the policies of the Department of Transportation.

Environmental Coordination Branch (G-WEP-2)

- Establishes and maintains liaison with appropriate Headquarters and Departmental Offices to ensure coordination of Coast Guard's environmental program.

- Represents the Coast Guard at meetings involving governmental agencies, the public and private sectors, and international organizations regarding general environmental matters.

Pollution Prevention and Enforcement Branch (G-WEP-3)

- Directs the Coast Guard's program to prevent and investigate pollution discharges into the marine environment.

Pollution Response Branch (G-WEP-4)

- Plans, develops, and implements the Coast Guard Program for pollution removal from the marine environment.

- Manages and coordinates the National Strike Force.

- Provides Department of Transportation membership in the National Response Team.

Surveillance and Monitoring Branch (G-WEP-5)

- Plans, develops, and implements Coast Guard programs to detect pollution in the marine environment.

National Response Center Staff (G-WEP-6)

- o Manages and operates the National Response Center to support the National Response Team in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan.

Environmental Impact Branch (G-WEP-7)

- o Plans, directs, and monitors a Coast Guard program to comply with the National Environmental Policy Act of 1969 (NEPA) and related legislation.
- o Plans, directs, and monitors a Coast Guard program concerned with the abatement of pollution from Coast Guard facilities (vessels, vehicles, aircraft, structures, and shore stations).

Port Safety and Law Enforcement Division (G-WLE)

- o Manages the Coast Guard Port Safety/Security Program for ports and navigable waterways of the United States.

Port Safety Branch (G-WLE-1)

- o Develops, manages, and monitors functions administered by the Captains of the Port and Port Safety stations including the administration of dangerous cargo regulations.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| U.S.C.G./EPA Liaison Officer | 202-755-0770 | -- |
| Marine Safety Council | 202-426-1616 | (G-CMC) |
| Office of Research and Development | 202-426-1040 | (G-D) |
| Office of Chief Counsel | 202-426-1616 | (G-L) |
| Regulations and Administrative Law Division | 202-426-1534 | (G-LRA) |
| Office of Merchant Marine Safety | 202-426-2200 | (G-M) |
| Cargo and Hazardous Materials Division | 202-426-2297 | (G-MHM) |
| Technical Advisory Staff | 202-426-2306 | (G-MHM) |
| Hazard Evaluation Branch | 202-426-2559 | (G-MHM-3) |

*FTS numbers are the same

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Merchant Vessel Inspection Division | 202-426-2178 | (G-MVI) |
| Merchant Vessel Personnel Division | 202-426-1500 | (G-MVP) |
| Office of Marine Environment and Systems | 202-426-2007 | (G-W) |
| Marine Environmental Protection Division | 202-426-2010 | (G-WEP) |
| Environmental Coordination Branch | 202-426-9573 | (G-WEP-2) |
| Pollution Prevention and Enforcement Branch | 202-426-9578 | (G-WEP-3) |
| Pollution Response Branch | 202-426-9568 | (G-WEP-4) |
| Surveillance and Monitoring Branch | 202-755-7938 | (G-WEP-5) |
| National Response Center Staff | 202-426-3300 | (G-WEP-6) |
| Environmental Impact Branch | 202-426-3300 | (G-WEP-7) |
| Port Safety and Law Enforcement Division | 202-426-1934 | (G-WLE) |
| Port Safety Branch | 202-426-1927 | (G-WLE-1) |

# STATUTORY AUTHORITIES

## Ports and Waterways Safety Act

### Public Law 92-340 46 U.S.C. § 391a (vessels) 33 U.S.C. § 1221 (ports)

The Ports and Waterways Safety Act is designed to provide adequate protection of the Nation's coastal areas and marine environment. It allows the Secretary of the Department in which the Coast Guard is operating (currently the Department of Transportation) to set standards of vessel design and safety and to establish measures for the safe transportation of potentially dangerous cargoes, including toxic substances. The Secretary is authorized to investigate any incidents involving damage to marine areas or ecosystems, and to ensure compliance with the provisions of the Act.

Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 101 | Authorizes Secretary to establish regulations and procedures for the safe storage and transportation of toxic substances on vessels in navigable U.S. waters. |
| sec. 103 | Permits Secretary to investigate accidents causing damage to the environmental quality of ports, harbors, or other coastal areas. |
| sec. 104 | Allows Secretary to establish regulations and other standards to enforce the Act. |
| sec.201(2) | Defines and sets standards for the transport of liquid cargo in bulk. |
| sec.201(3) | Permits Secretary to establish rules governing vessel design and maintenance. |
| sec.201(4) | Provides for consultation with other Federal agencies involved in marine environmental protection. |

## Regulatory Options Available Under Statute

- Control vessel traffic and operation
- Establish vessel safety requirements
- Set standards for transport of dangerous cargoes
- Limit vessel activity in defined waterfront safety zones
- Restrict the transportation of hazardous materials (in bulk cargo from navigable waters)
- Ban the transportation of hazardous materials in bulk cargo from navigable waters

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

1. A petition to issue, amend, or repeal a regulation is received or is proposed as a result of internal action.
2. Depending on the complexity and/or urgency, an Advance Notice of Proposed Rulemaking (ANPRM) may be published in the Federal Register. Otherwise, a Notice of Proposed Rulemaking (NPRM) is published, comments are solicited, and public hearings are held.
3. The final rule is cleared through the Marine Safety Council, the Commandant, the Secretary of Transportation, and the Department Regulation Council.
4. The rule is delivered and published in the Federal Register.

## EXISTING REGULATIONS

Ports and Waterways Safety Act

| | | |
|---|---|---|
| (ports) | 33 U.S.C. § 1221 | 33 CFR 160-165 |
| (vessels) | 46 U.S.C. § 391a | 33 CFR 1, 3, 151, 157, 164<br>46 CFR 2-197 |

# TOXICS-RELATED ACTIVITIES*

## Carriage of Bulk Liquid Hazardous Cargoes--General

Statutes: 33 U.S.C. § 1321; 46 U.S.C. §§ 325, 391a, 416, 1655; 49 U.S.C. § 1803

Regulations: 46 CFR 150, 151, 153, 154 (Subchapter "O")

Responsible Office: G-MHM (Cargo and Hazardous Materials Division)

Description:

a. 46 CFR 151 regulates the carriage of bulk liquid hazardous cargoes by barge.

b. 46 CFR 153 regulates the carriage of hazardous liquids by tank vessel,

c. 46 CFR 154 regulates carriage of liquified gases by tank vessels.

## Certification of Personnel Involved with Transporting Bulk Liquid Hazardous Cargoes by Barge

Statutes: 46 U.S.C. §§ 375, 391a, 416

Regulations: 33 CFR 155, 46 CFR 12, 30, 31, 35, 70, 90, 98, 105, 151, 157

Responsible Office: G-MVP (Merchant Vessel Personnel Division)

Description:

a. 46 CFR 157 states the general manning requirements for commercial vessels.

b. Licensed officers or "tankermen" are required to oversee cargo transfer operations.

New Items: Regulations to streamline and state new licensing qualifications are in progress.

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*Included are those activities identified as toxics-related from the information provided by each agency. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxic Integration staff.

## Transfer Operations Involving Bulk Liquid Hazardous Substances

Statutes: 33 U.S.C. § 1321

Regulations: 33 CFR 124, 126, 154, 155, 156; 40 CFR 117

Responsible Office: G-WEP (Marine Environmental Protection Division), G-WLE (Port Safety and Law Enforcement Division)

Description: 33 CFR 124 and 40 CFR 117 designate the hazardous substances regulated under this program (not all listed are permitted to be shipped in bulk).

New Items: Streamlining, consolidation, and addition of hazardous substances to the present regulations (which speak only to oil) are in progress. Development of a comprehensive regulatory package to address transfer operations of hazardous substances.

## Notification to the Captain of the Port, USCG, of the Existence of Hazardous Conditions Aboard a Vessel and/or Marine Casualties

Statutes: 33 U.S.C. §§ 1223, 1228; 46 U.S.C. § 391a

Regulations: 33 CFR 124, 161

Responsible Office: G-WLE (Port Safety and Law Enforcement Division)

Description: 33 CFR 124 requires advance notice of the arrival or departure of vessels carrying "cargoes of particular hazard" and defines cargoes of particular hazard.

New Items:

a. To permit advance contingency planning by persons responsible for safety of ports, prior to port entry, vessels will be required to report conditions which may adversely affect the operation of the vessel.

b. The regulations are to be consolidated and streamlined in 33 CFR 161. Interim final regulations were published in November 1979.

c. IMCO is studying additional requirements for vessels in international waters to report marine casualties to the nearest country. Regulations implementing the IMCO convention will be added to 33 CFR 161 upon ratification.

## Ocean Dumping Surveillance

Statute: 16 U.S.C. § 1431; 33 U.S.C. §§ 1401, 1417, 1418

Regulations: 33 CFR 158 (Vacant); 40 CFR 220 thru 229

Responsible Office: G-WEP (Marine Environmental Protection Division)

Description:

a. 40 CFR 220 through 229 describe the permit system established by EPA to regulate ocean dumping of all materials except dredged material.

b. 33 CFR 323-325 describes the permit system established by the Army Corps of Engineers (ACOE) to regulate ocean dumping of dredged material.

c. 33 CFR 158 will contain the regulations covering electronic surveillance equipment required to assist the USCG in surveillance of ocean dumps which are made in accordance with the terms of permits issued by EPA and ACOE, and by authorizations issued by ACOE for ocean dumping of dredged materials.

New Items: Dumping surveillance regulations were proposed during December 1979.

## Inspection of Foreign Flag Tank Ships

Statute: 33 U.S.C. § 1321; 46 U.S.C. § 391a; 49 U.S.C. § 1803

Regulation: None

Responsible Office: G-MVI (Marine Investigation Division)

Description: The series of tank ship explosions which occurred in the winter of 1976-77 prompted an immediate and singularly successful unilateral inspection program of cargo-handling systems on foreign flag tank ships entering U.S. ports.

## Response to Spills of Oil or Hazardous Substances

Statute: 33 U.S.C. § 1321

Regulations: 33 CFR 153; 40 CFR 110, 117, 1510

Responsible Office: G-WEP (Marine Environmental Protection Division)

Description:

a. 40 CFR 110 defines oil.

b. 40 CFR 116 designations of hazardous substances.

c. 40 CFR 117 defines reportable quantities of hazardous substances.

d. 40 CFR 1510 is the National Contingency Plan.

e. 33 CFR 153 is the USCG implementation of the Clean Water Act in regard to response activity under the National Contingency Plan, and management of the pollution revolving fund.

New Items: The National Contingency Plan was revised on March 19, 1980, to conform to the Clean Water Act (as amended 1977). See 45 FR 17832.

# ENVIRONMENTAL PROTECTION AGENCY

401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

EPA was created through an executive reorganization plan designed to consolidate certain Federal Government environmental activities into a single agency. The plan (Reorganization Plan No. 3 of 1970) was sent by the President to Congress on July 9, 1970, and EPA was established as an Independent Agency in the Executive Branch on December 2, 1970.

EPA was formed by combining 15 components from 5 departments and independent agencies. Water quality responsibilities were transferred from the Interior Department (the Federal Water Quality Administration) and the (former) Department of Health, Education, and Welfare* (the Bureau of Water Hygiene). Other activities transferred from HEW included the National Air Pollution Control Administration and the Bureau of Solid Waste Management.

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*As of May 4, 1980, HEW was divided into two new departments--the Department of Health and Human Services and the Department of Education.

In addition, EPA acquired the Department of Agriculture's authority to register pesticides and to regulate their use; the Food and Drug Administration's authority to set tolerance levels for pesticides which occur in or on food and to monitor compliance with those limits; and a portion of the Department of Interior's pesticides research program.

Finally, EPA assumed some of the authorities of the former Atomic Energy Commission and HEW for setting environmental radiation protection standards. The Agency also absorbed the duties of the Federal Radiation Council.

Organizationally, EPA is headed by an Administrator, who is supported by a Deputy Administrator and six Assistant Administrators (see chart). Three of the Assistant Administrators are responsible for "functionalized" activities, i.e., activities which cut across all media programs. These activities are planning and management, enforcement, and research and development. The remaining program activities have been grouped under three other Assistant Administrators on a media or pollutant basis, e.g., water pollution, air pollution, solid waste, toxic substances, etc. The activities carried out by these Offices are primarily policy development, preparation and promulgation of regulations, and support and evaluation of regional activities.

Six Offices within EPA are highlighted in this publication. They are the Office of Pesticide Programs and the Office of Toxic Substances which are located within the Office of Pesticides and Toxic Substances; the Office of Water Planning and Standards, the Office of Solid Waste, and the Office of Drinking Water, which are located within the Office of Water and Waste Management; and the Offices of Air Quality Planning and Standards and Mobile

Source Air Pollution Control* which are part of the Office of Air, Noise, and Radiation.

Included in this introductory section on EPA is a description of the regulatory development process within the Agency. Since this process is used by all of the EPA Offices, it was decided to place the description here and refer to it in the Regulatory Development Section of each Office.

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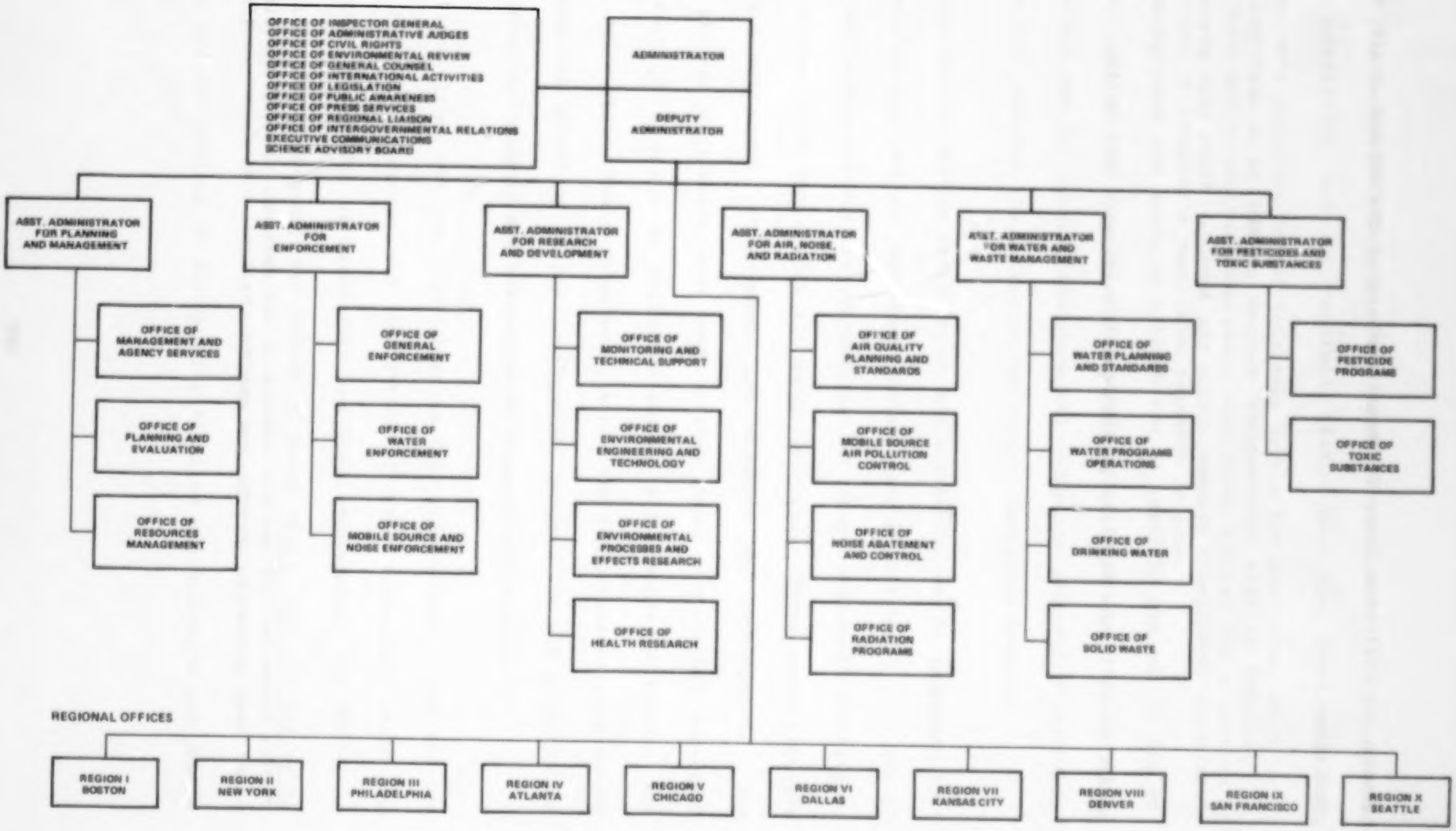
*NOTE: These two Offices are treated in one section, whereas the other Offices are developed in separate sections.

# U.S. ENVIRONMENTAL PROTECTION AGENCY

## Organizational Chart


OFFICE OF INSPECTOR GENERAL
OFFICE OF ADMINISTRATIVE JUDGES
OFFICE OF CIVIL RIGHTS
OFFICE OF ENVIRONMENTAL REVIEW
OFFICE OF GENERAL COUNSEL
OFFICE OF INTERNATIONAL ACTIVITIES
OFFICE OF LEGISLATION
OFFICE OF PUBLIC AWARENESS
OFFICE OF PRESS SERVICES
OFFICE OF REGIONAL LIAISON
OFFICE OF INTERGOVERNMENTAL RELATIONS
EXECUTIVE COMMUNICATIONS
SCIENCE ADVISORY BOARD
ADMINISTRATOR
DEPUTY ADMINISTRATOR
ASST. ADMINISTRATOR FOR PLANNING AND MANAGEMENT
OFFICE OF MANAGEMENT AND AGENCY SERVICES
OFFICE OF PLANNING AND EVALUATION
OFFICE OF RESOURCES MANAGEMENT
ASST. ADMINISTRATOR FOR ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
OFFICE OF WATER ENFORCEMENT
OFFICE OF MOBILE SOURCE AND NOISE ENFORCEMENT
ASST. ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
OFFICE OF MONITORING AND TECHNICAL SUPPORT
OFFICE OF ENVIRONMENTAL ENGINEERING AND TECHNOLOGY
OFFICE OF ENVIRONMENTAL PROCESSES AND EFFECTS RESEARCH
OFFICE OF HEALTH RESEARCH
ASST. ADMINISTRATOR FOR AIR, NOISE, AND RADIATION
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
OFFICE OF MOBILE SOURCE AIR POLLUTION CONTROL
OFFICE OF NOISE ABATEMENT AND CONTROL
OFFICE OF RADIATION PROGRAMS
ASST. ADMINISTRATOR FOR WATER AND WASTE MANAGEMENT
OFFICE OF WATER PLANNING AND STANDARDS
OFFICE OF WATER PROGRAMS OPERATIONS
OFFICE OF DRINKING WATER
OFFICE OF SOLID WASTE
ASST. ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
OFFICE OF TOXIC SUBSTANCES
REGIONAL OFFICES
REGION I BOSTON
REGION II NEW YORK
REGION III PHILADELPHIA
REGION IV ATLANTA
REGION V CHICAGO
REGION VI DALLAS
REGION VII KANSAS CITY
REGION VIII DENVER
REGION IX SAN FRANCISCO
REGION X SEATTLE

# REGULATORY DEVELOPMENT

At the onset of the regulatory development process, all new EPA regulations are classified as either "Significant" or "Specialized." (See figure 1) This classification is done by the lead office with the concurrence of the Office of Planning and Management. Approximately half of the current regulations are labeled "Significant" and follow the uniform development process outlined below. All other regulations are referred to as "Specialized" and follow separate specialized procedures. Both classes of regulations include provisions for public review and comment.

## Chart 1

Definitions of Terms Used in the EPA Regulatory Development Process

### Significant Regulations

All new regulations are presumed to be Significant unless they fall into one of the exclusion categories listed under Specialized Regulations. Significant Regulations follow the formal regulatory development procedures.

### Specialized Regulations

Regulations which are not subject to formal regulatory development procedures. These include: regulations that are administrative or procedural in nature and do not affect certain aspects of EPA programs; minor amendments to existing regulations; regulatory actions resulting from detailed Congressional mandates; regulations which the lead office Assistant Administrator designates as not sufficiently important to require formal development procedures; EPA actions on regulations developed by State and local government; and certain pesticide-related actions.

### Lead Office

The Assistant Administrator for the relevant program (the Office of Air, Noise, and Radiation, the Office of Enforcement, the Office of Pesticides and Toxic Substances, or the Office of Water and Waste Management) has the lead responsibility for initiating and writing most new regulations.

## Senior Management

This group includes the Administrator, Deputy Administrator, Assistant Administrators, Regional Administrators, General Counsel, and appropriate Staff Office Directors.

## Major Regulations

A regulation will be classified as Major if it is likely to: address a major health or ecological problem; result in a major health, ecological, or economic impact; cause substantial urban impact; initiate a substantial regulatory program or change in policy; cause a substantial impact on another EPA program or another Federal agency program; cause a substantial change in the scope of State-administered environmental programs; cause a disproportionate impact on a particular region of the United States; and/or implement a regulatory program central to the basic purpose of the statute under which it is adopted. Major regulations will receive extra attention from senior Agency management.

## Routine Regulations

All regulations not classified as Major regulations.

## Work Groups

This is a group of specialists drawn from various offices within EPA to advise and assist the lead office in preparing each significant regulation and its support materials.

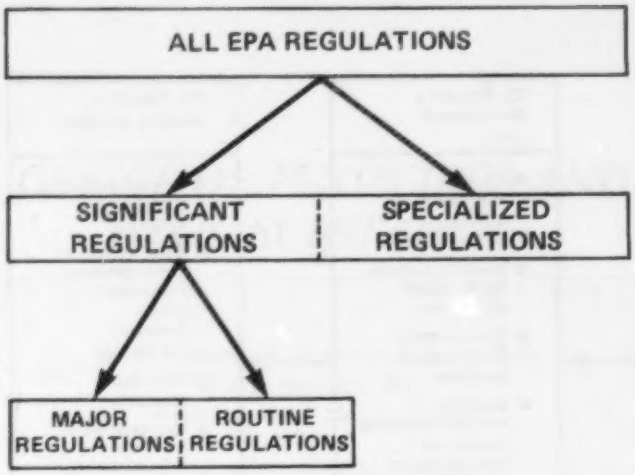
## Steering Committee

This is a continuing group representing the six Assistant Administrators, General Counsel, and appropriate Office Directors on the Administrator's staff. It oversees the mechanics of the process and conducts the first internal review of materials prepared by the lead office.

## Red Border Review

This is an internal review by all Assistant Administrators, General Counsel and chief Staff Office Directors. The heads of EPA's ten regional offices (Regional Administrators) also have an opportunity to submit comments. A full review takes 3 weeks.

Figure 1. Priority Classifications for EPA Regulations

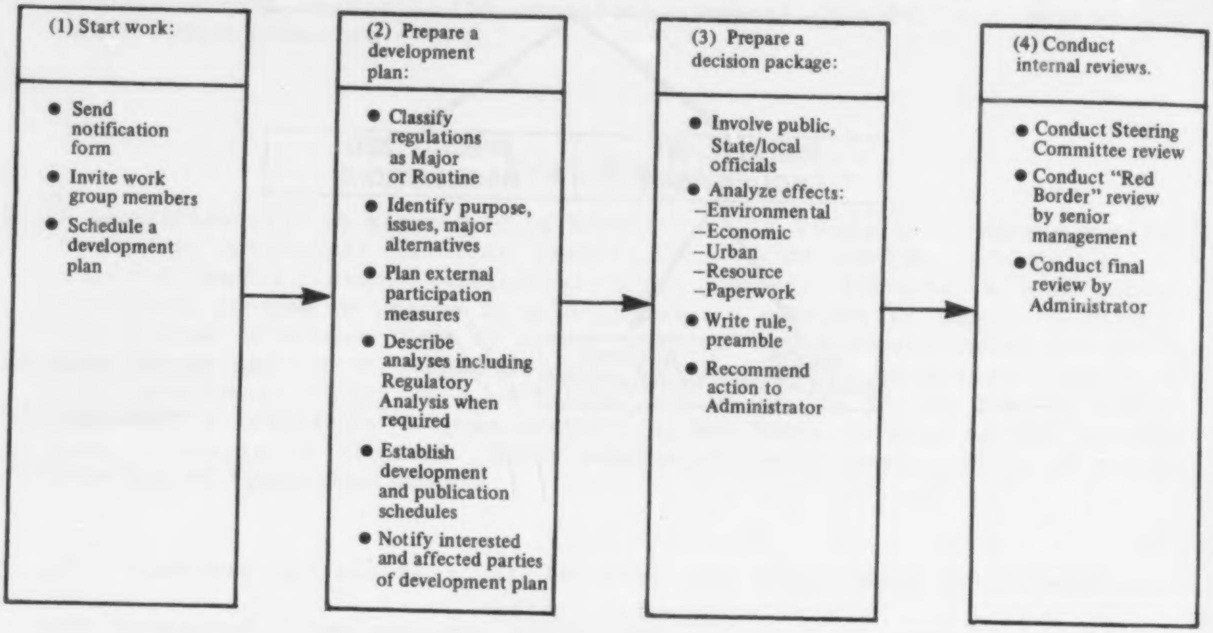

ALL EPA REGULATIONS
SIGNIFICANT REGULATIONS
SPECIALIZED REGULATIONS
MAJOR REGULATIONS
ROUTINE REGULATIONS

Significant regulations are produced in a multistage process: (1) notification stage, in which the lead office notifies senior management that work is starting on a new regulation, (2) preparation of a development plan, (3) preparation of a decision package, which also includes writing the preamble and regulation, and (4) conducting a three-part internal review. Each regulation goes through the third and fourth stages twice, first as a proposal and again in final form.

For internal management purposes, EPA further divides all Significant regulations into two classes, Major and Routine. Both types follow the uniform regulation development process. However, Major regulations will receive extra attention from senior Agency management.

The regulatory development process (i.e., Significant Regulations) within EPA is summarized in figure 2. A more detailed description of this process can be found in "Improving Environmental Regulations," 44 FR 30988.

Figure 2. Stages in the Development of Significant EPA Regulations


(1) Start work:
• Send notification form
• Invite work group members
• Schedule a development plan
(2) Prepare a development plan:
• Classify regulations as Major or Routine
• Identify purpose, issues, major alternatives
• Plan external participation measures
• Describe analyses including Regulatory Analysis when required
• Establish development and publication schedules
• Notify interested and affected parties of development plan
(3) Prepare a decision package:
• Involve public, State/local officials
• Analyze effects:
–Environmental
–Economic
–Urban
–Resource
–Paperwork
• Write rule, preamble
• Recommend action to Administrator
(4) Conduct internal reviews.
• Conduct Steering Committee review
• Conduct "Red Border" review by senior management
• Conduct final review by Administrator

# *OFFICE OF PESTICIDES AND TOXIC SUBSTANCES*

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

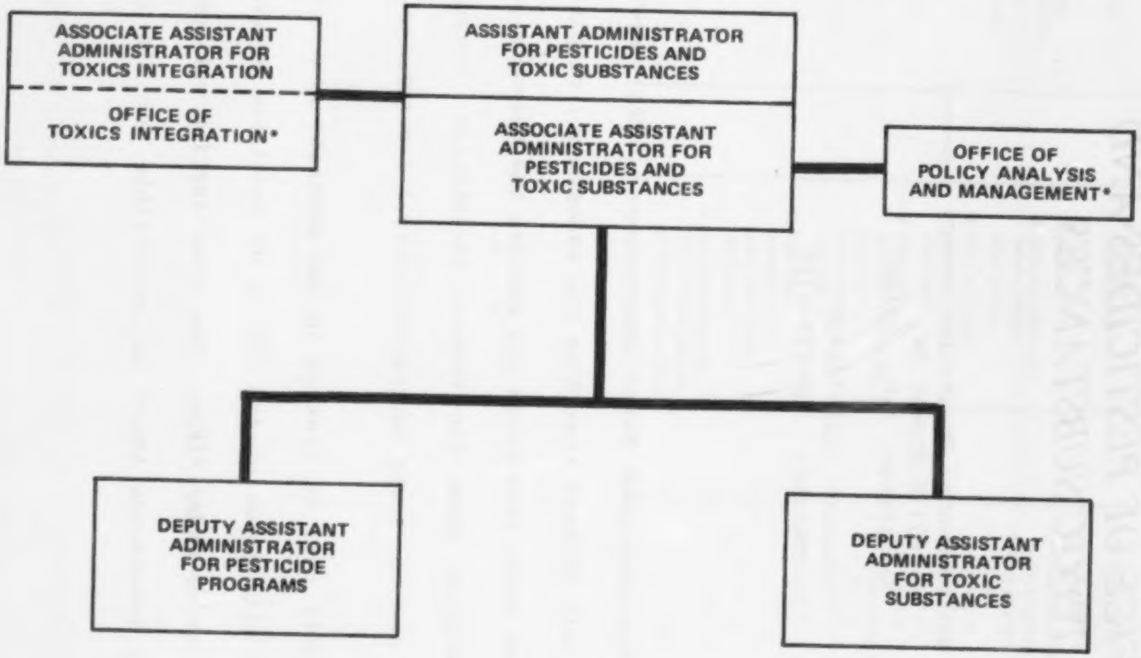
The Office of Pesticides and Toxic Substances (OPTS) advises the Administrator of EPA on all matters regarding the assessment, regulation, and control of pesticides and toxic substances and manages the Agency's pesticides and toxic substances program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

The activities of OPTS will be treated in two separate sections of this directory. One section will focus on the Office of Pesticide Programs which handles all Agency activities under FIFRA. The other section will concentrate on the Office of Toxic Substances which is responsible for EPA activities under TSCA.

ENVIRONMENTAL PROTECTION AGENCY

# OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

ORGANIZATIONAL CHART


ASSOCIATE ASSISTANT ADMINISTRATOR FOR TOXICS INTEGRATION
OFFICE OF TOXICS INTEGRATION*
ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
ASSOCIATE ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF POLICY ANALYSIS AND MANAGEMENT*
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDE PROGRAMS
DEPUTY ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES

*NOTE: The functions of these two offices are given on the following page.

# ORGANIZATION

## OFFICE OF TOXICS INTEGRATION

- Establishes policies, priorities and procedures for the integration and coordination of Agency and Federal Activities concerning toxic substances.
- Conducts studies and analyses of Agency and other Federal priority-setting mechanisms for chemicals and recommends regulatory and nonregulatory approaches for chemical control.
- Oversees evaluation of OPTS and Agencywide decisionmaking criteria for ordering and ranking toxic chemicals for risk assessment and regulation.
- Evaluates TSCA and other EPA statutes in terms of policy consistency and efficacy of implementation with regard to integrated approaches for chemical information collection and dissemination and chemical regulatory control mechanisms.
- Provides staff and operating support to the Toxic Substances Priorities Committee (TSPC) to assist the TSPC in developing and monitoring policies and procedures to coordinate and integrate toxic substances activities.
- Oversees the development of the Chemical Substances Information Network (CSIN).
- Works with the Interagency Regulatory Liaison Group (IRLG) Agencies to integrate Federal toxic substances information development, assessment and control activities.
- Develops policies and procedures to articulate State and Regional relationships to TSCA implementation.
- Implements OPTS public participation programs.
- Develops and disseminates educational and other mateials designed to increase awareness of the objectives and mechanisms provided under TSCA, FIFRA, and other EPA statutes for toxic substances control.
- Coordinates all international aspects of TSCA and FIFRA.

## OFFICE OF POLICY ANALYSIS AND MANAGEMENT

- Advises the Assistant Administrator of OPTS on matters of policy, program evaluation, management, resource allocation, and administration.

- Serves as the focal point for all OPTS documents published in the Federal Register.

# OFFICE OF TOXIC SUBSTANCES

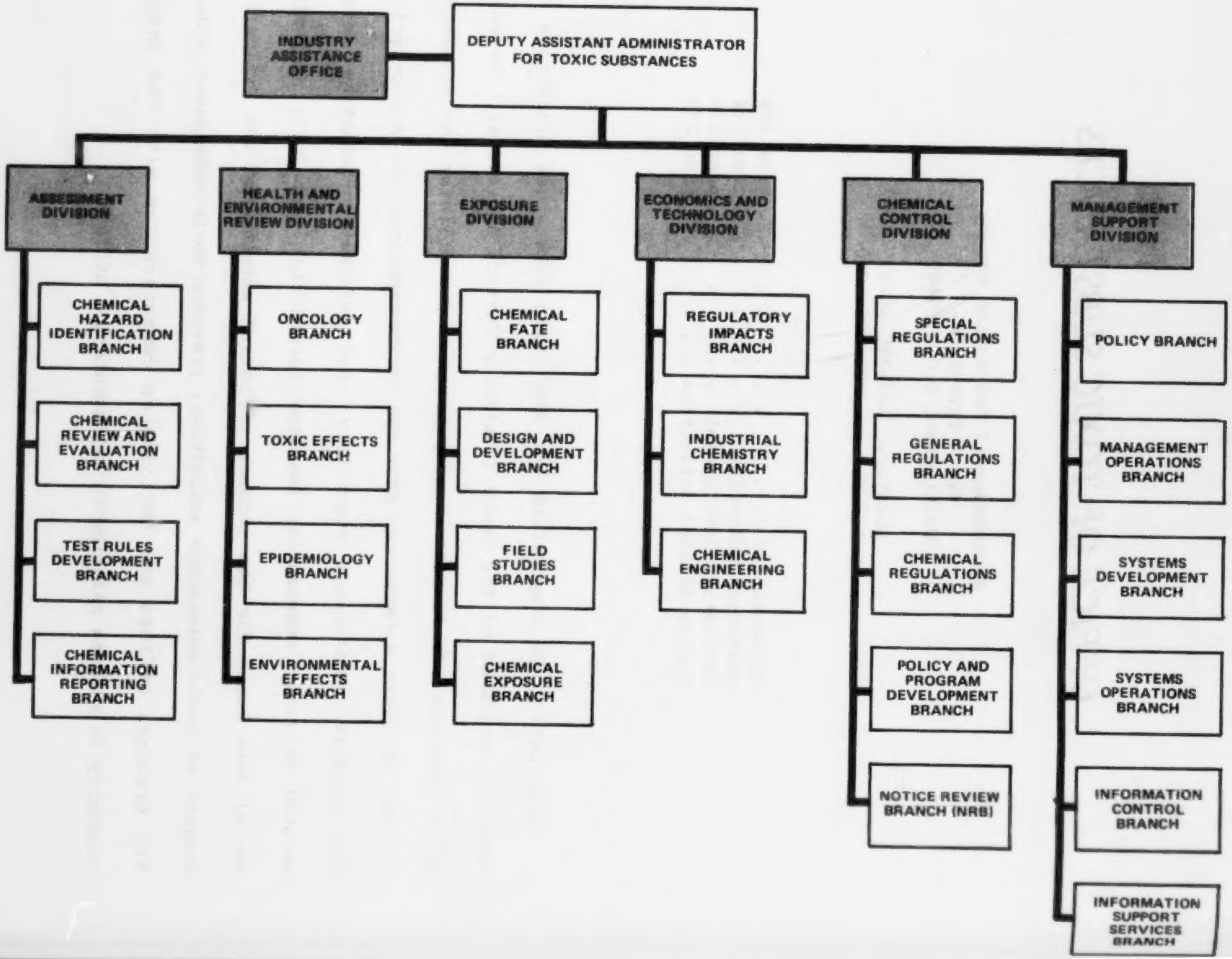
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

Organization . . . . . . . . . . . . . . . page 209
Statutory Authority . . . . . . . . . . . page 212
Regulatory Development . . . . . . . . . page 218
Toxics-Related Activities . . . . . . . page 219

This Office is responsible for the toxic substances activities of the Agency as mandated by the Toxic Substances Control Act (TSCA). As such, the Office develops and operates Agency programs and policies for assessment and control of toxic substances; develops recommendations for Agency priorities for research monitoring, regulatory, and information-gathering activities related to toxic substances; develops scientific, technical, economic, and social data bases for the conduct of hazard assessments and evaluations in support of toxic substances activities; provides toxic substances guidance to EPA Regional Offices and coordinates communication with the industrial community on matters relating to implementation of TSCA.

# ENVIRONMENTAL PROTECTION AGENCY
# OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
# OFFICE OF TOXIC SUBSTANCES
## ORGANIZATIONAL CHART


INDUSTRY ASSISTANCE OFFICE
DEPUTY ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES
ASSESSMENT DIVISION
CHEMICAL HAZARD IDENTIFICATION BRANCH
CHEMICAL REVIEW AND EVALUATION BRANCH
TEST RULES DEVELOPMENT BRANCH
CHEMICAL INFORMATION REPORTING BRANCH
HEALTH AND ENVIRONMENTAL REVIEW DIVISION
ONCOLOGY BRANCH
TOXIC EFFECTS BRANCH
EPIDEMIOLOGY BRANCH
ENVIRONMENTAL EFFECTS BRANCH
EXPOSURE DIVISION
CHEMICAL FATE BRANCH
DESIGN AND DEVELOPMENT BRANCH
FIELD STUDIES BRANCH
CHEMICAL EXPOSURE BRANCH
ECONOMICS AND TECHNOLOGY DIVISION
REGULATORY IMPACTS BRANCH
INDUSTRIAL CHEMISTRY BRANCH
CHEMICAL ENGINEERING BRANCH
CHEMICAL CONTROL DIVISION
SPECIAL REGULATIONS BRANCH
GENERAL REGULATIONS BRANCH
CHEMICAL REGULATIONS BRANCH
POLICY AND PROGRAM DEVELOPMENT BRANCH
NOTICE REVIEW BRANCH (NRB)
MANAGEMENT SUPPORT DIVISION
POLICY BRANCH
MANAGEMENT OPERATIONS BRANCH
SYSTEMS DEVELOPMENT BRANCH
SYSTEMS OPERATIONS BRANCH
INFORMATION CONTROL BRANCH
INFORMATION SUPPORT SERVICES BRANCH

# ORGANIZATION

## INDUSTRY ASSISTANCE OFFICE

- Informs industry of EPA policy and regulatory positions under TSCA.
- Identifies industry needs and problems in meeting EPA's toxic substances requirements and promotes discussion between industry and EPA on toxic substances.
- Advises the Deputy Assistant Administrator on industry activities.
- Assists Regional Offices in responding to inquiries from industry.

## ASSESSMENT DIVISION

- Identifies and manages the scientific evaluation of chemical risks to human health and the environment.
- Performs preliminary evaluations of the types of hazards and degree of risks reflected in the data submitted under TSCA sections 4, 5, and 8.
- Develops and implements reporting and recordkeeping rules and guidelines under TSCA section 8.
- Manages (in support of the Chemical Control Division) the scientific evaluation of chemical problems being considered for regulatory or nonregulatory action.
- Develops and implements procedures for the selection of specific chemicals or categories for testing under section 4.

## HEALTH AND ENVIRONMENTAL REVIEW DIVISION

- Responsible for detailed assessment of harmful effects of chemicals on human health and on the environment in support of OTS regulatory activities.
- Reviews, validates, and evaluates test data submitted by industry as well as other available information relevant to harmful effects of chemicals on human health and the environment in support of the risk assessment activities of the Assessment Division.

- Performs scientific assessments of toxicity and other chemical hazards to human health and the environment.

- Identifies and develops new methods and techniques for laboratory testing, epidemiological study, and evaluation of chemical hazards to human health and the environment through studies that are planned within the Agency's Research Committee System.

## EXPOSURE EVALUATION DIVISION

- Supports OTS detailed risk assessment activities through an integrated assessment of chemical exposure to humans and the environment.

- Develops standards, guidance, and rule development support to the Chemical Control Division and the Assessment Division for chemical, physical, and persistence properties testing, analytical methods, field sampling, and other exposure-related data and studies, under TSCA sections 4, 5, and 8.

- Reviews, evaluates, and validates data submitted by industry and other available information relevant to chemical exposure to humans and the environment.

- Performs scientific assessments of chemical exposure to humans and the environment in support of the risk assessment activities of the Assessment Division.

## ECONOMICS AND TECHNOLOGY DIVISION

- Provides economic, engineering, and industrial chemistry support to the Chemical Control Division for TSCA sections 5, 6, and 7 rulemaking, and to the Assessment Division for TSCA sections 4 and 8 rulemaking.

- Participates in the development of regulations within OTS ensuring that economic and technical feasibility issues are fully considered.

- Conducts assessments of the overall economic, engineering, and industrial chemistry impacts of TSCA regulatory actions and OTS nonregulatory actions.

## CHEMICAL CONTROL DIVISION

- Selects and implements appropriate regulatory and nonregulatory controls for existing and new chemicals or chemical uses found to present or to have the potential for presenting unreasonable risks to human health or the environment.

- Manages the regulatory evaluation and decisionmaking process for chemicals subject to manufacturing or processing notices under section 5, subject to citizens' petitions under section 21, seeking action under sections 4, 5, or 6, or identified as candidates for control action through the efforts of the Assessment Division.

- Develops generic and chemical-specific rules under sections 5, 6, or 7 of TSCA.
- Evaluates the need for and develops chemical-specific orders and notices pursuant to sections 5(e), 5(f), 6(b), and 9 and, in cooperation with the Office of General Counsel, support for court actions under sections 5(e), 5(f), and 7.

## MANAGEMENT SUPPORT DIVISION

- Supports OTS in Officewide policy analysis, program evaluations, operational policy, management information systems, budget, administration, and information support functions.
- Supports other OTS divisions in management information systems, program evaluation, and information support functions.
- Designs and operates a Chemicals in Commerce Information System to handle data collected in complying with TSCA.
- Develops and maintains an inventory of chemical substances and mixtures manufactured or processed in the United States.
- Develops policies and procedures for State grants program and for handling State requests for exemptions from Federal preemption.

# STATUTORY AUTHORITY

## The Toxic Substances Control Act

Public Law 94-469 15 U.S.C. § 2601

In 1971, the President's Council on Environmental Quality developed a legislative proposal for coping with the increasing problems of toxic substances. Over the next 5 years, Congress held many hearings, debated and amended the provisions in committee, failed to resolve the differences between the House and Senate bills in the 92nd and 93rd Congresses, and finally passed the present legislation in the fall of 1976. The law grants the U.S. Environmental Protection Agency (EPA) significant new authority to anticipate and address chemical risks.

The Toxic Substances Control Act authorizes EPA to obtain information from industry on the production, use, health effects, and other matters concerning chemical substances and mixtures. If warranted after considering the costs, risks, and benefits of a substance, EPA may regulate its manufacture, processing, distribution in commerce, use, and disposal. Pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics are exempted from the Act; these products are currently handled under other laws.

## Key Sections of Act--Toxics Focus

### Section 4--Testing of Chemical Substances and Mixtures

sec. 4(a) The Administrator shall require by rule the testing of any chemical substance or mixture whose manufacture, distribution, processing, use, or disposal is suspected of presenting an unreasonable risk of injury to health or environment, and about which insufficient data exist to adjudge that risk.

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| sec. 4(b) | States the requirements for and effects for which testing rules can be developed under subsection 4(a). |
| sec. 4(c) | Provides for exemptions to the testing rules developed under subsection 4(a). |
| sec. 4(e) | Provides for the establishment, by committee, of a priority list of chemical substances or mixtures (not to exceed 50) for consideration in the promulgation of rules under subsection 4(a). (Note: This function is performed by the TSCA Interagency Testing Committee [ITC] which was formed in February 1977 and includes representatives from eight Federal agencies.) |
| sec. 4(f) | Upon receipt of any test data submitted under this Act, or any other available information which indicates that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to humans from cancer, gene mutations, or birth defects, the Administrator shall initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk. |
| sec. 4(g) | A manufacturer or processor may petition for test standards to be set by the Administrator. |

## Section 5--Manufacturing and Processing Notices (Premanufacturing Notification)

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| sec. 5(a) | Section 5 requires a manufacturer or processor to notify EPA 90 days before producing either a new chemical substance, i.e., not on the TSCA Inventory of existing chemicals or an existing chemical intended to be used in a "significantly" new way. |
| sec. 5(b) | Describes the instances in which a person subject to the notification requirement under subsection 5(a) must submit test data to the Administrator before the manufacture or processing of the substance can begin. |
| sec. 5(c) | Allows the Administrator, for good cause, to extend the notice review period prescribed by subsections 5(a) and 5(b) for a period not to exceed, in the aggregate, 90 days. |
| sec. 5(d) | Requires the Administrator to publish in the Federal Register all notices received under subsection 5(a) together with data describing health and environmental effects. |
| sec. 5(e) | Sets out the procedures under which the Administrator can prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new substance, or significant new use of an existing substance when there is insufficient information to evaluate the health and environmental effects of the substance. |

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| sec. 5(f) | Requires the Administrator to take immediate action to prohibit or limit human or environmental exposure to a new chemical substance, or significant new use of an existing chemical substance, if he finds a reasonable basis to conclude that the substance poses an unreasonable risk. |
| sec. 5(g) | If the Administrator does not prohibit or limit the manufacturing, processing, etc., of certain new chemicals or new uses of existing chemicals (substances that are listed under subsection 5(b)), then the Administrator must publish his reasons for not initiating the action. |
| sec. 5(h) | Provides for exemptions to subsections 5(a) and 5(b). |

## Section 6--Regulation of Hazardous Chemical Substances and Mixtures

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| sec. 6(a) | The Administrator may prohibit or limit the manufacture, processing, distribution, use, or disposal of a chemical substance or mixture that presents an unreasonable risk of injury to health or the environment. |
| sec. 6(b) | Allows the Administrator to require the revision of inadequate quality control procedures utilized in the manufacture or processing of chemical substances or mixtures. |
| sec. 6(c) | Details the procedures for promulgating rules under subsection 6(a). |
| sec. 6(d) | Allows the Administrator to make a proposed rule immediately effective upon its publication in the Federal Register. |
| sec. 6(e) | Requires the Administrator to prescribe regulations for the labeling and disposal of polychlorinated biphenyls (PCBs). Bans the manufacture, processing, distribution, and use of PCBs in other than a totally enclosed manner by July 1979. |

## Section 7--Imminent Hazards

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| sec. 7(a) | Authorizes the Administrator to bring suit in a U.S. district court for seizure, relief, or both, of any imminently hazardous substance or mixture or article containing it. |
| sec. 7(b) | The district courts will have jurisdiction to grant temporary or permanent relief for actions brought under subsection 7(a). |
| sec. 7(d) | Concurrent with or as soon as possible after the filing of an action under subsection 7(a) and, where appropriate, the Administrator shall initiate rulemaking under subsection 6(a). |
| sec. 7(f) | Defines an imminently hazardous chemical substance or mixture as that which presents an unreasonable risk of serious or widespread injury to health or the environment that is likely to occur before a section 6 action can protect against the risk. |

## Section 8--Reporting and Retention of Information

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| sec. 8(a) | Allows the Administrator to promulgate rules for industry (excludes small manufacturers and processors) reporting and retention of information on the manufacture, processing, use, and disposal of chemical substances, byproducts produced, and estimates of the number of people exposed in the workplace. |
| sec. 8(b) | Requires the publication of an inventory of chemical substances manufactured or processed in the United States. |
| sec. 8(c) | Requires manufacturers, processors, and distributors to keep records of and submit information on allegations of significant adverse reactions to health and the environment caused by chemicals. |
| sec. 8(d) | Requires manufacturers, processors, and distributors to submit, upon request, health and safety studies to EPA. |
| sec. 8(e) | Requires manufacturers, processors, and distributors to immediately notify the Administrator if they have information that reasonably supports the conclusion that a substance or mixture poses a substantial risk to health or the environment. |

## Section 9--Relationship to Other Federal Laws

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| sec. 9(a) | Establishes the relationship between the Act and Federal laws not administered by the Administrator. |
| sec. 9(a)(2) | Authorizes the publication of a report if the Administrator determines that risk may be prevented or significantly reduced by another law. |
| sec. 9(b) | Establishes the relationship between this Act and other laws administered in whole or in part by the Administrator. |
| sec. 9(d) | Requires that the Administrator consult and coordinate with other Federal agencies to avoid duplication and overlap. |

## Section 10--Research, Development, Collection, Dissemination, and Utilization of Data

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| sec. 10(a) | Requires the Administrator to conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. |
| sec. 10(b) | Authorizes the establishment of an interagency committee whose primary responsibility shall be to design an efficient system for the collection, dissemination, and use of data submitted to the Administrator under this Act. |

## Section 12--Exports

sec. 12(a) Chemical substances or mixtures manufactured or processed solely for export from the United States are exempt from the Act (except for the reporting requirements under section 8) if proper labeling shows they are intended for export use only.

sec. 12(b) Requires exporters to notify EPA when exporting chemicals for which certain section 4, 5, 6, or 7 actions have been taken. The Agency must in turn notify the country of import of the EPA regulatory action and of the availability of test data.

## Section 13--Imports

sec. 13(a) Authorizes the Secretary of the Treasury to refuse entry of any chemical substance, mixture, or article containing same if it fails to comply with any rule promulgated under this Act, or, if it is in violation of section 5 or 6, a rule or order under section 5 or 6, or an order or civil action brought under section 5 or 7.

## Section 14--Disclosure of Data

sec. 14(a) Any information obtained under TSCA which qualifies as a trade secret or as commercial or financial information must be kept confidential by EPA. An exception may be made where necessary to protect health or the environment.

sec. 14(b) An exception to confidentiality requirements may also be made for studies which are submitted concerning health and safety effects of certain chemicals.

sec. 14(c) Any person who submits information to EPA under TSCA may claim that it should be given confidential treatment, and is entitled to receive advance notice if EPA decides not to honor the claim.

sec. 14(d) Federal employees who knowingly disclose confidential information to persons who are not authorized to receive it are guilty of a misdemeanor and may be subject to a $5,000 fine and/or imprisonment for 1 year.

sec. 14(e) All information obtained under TSCA must be made available to committees of Congress, regardless of any claim of confidentiality.

## Section 21--Citizen's Petitions

sec. 21(a) States that any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under subsection 5(e) or 6(b)(2).

sec. 21(b) Details the procedures to be followed.

Regulatory Options Available Under Statute

- EPA may prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical. Such action can range from a labeling requirement to a complete ban.

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

For a discussion of the regulatory development process within EPA, see page 199 of this publication.

## EXISTING REGULATIONS

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| Toxic Substances Control Act | 40 CFR 710-762 |

# TOXICS-RELATED ACTIVITIES

Within the Office of Toxic Substances, toxics-related activities center on implementing the major provisions of TSCA. Specifically, these include those activities dealing with information gathering and dissemination, testing, premanufacture notification, and chemical control. Brief summaries of these activities are included here. More detailed information can be obtained from the Third Annual Report (1979) on the Administration of the Toxic Substances Control Act which is available from the Industry Assistance Office (in Washington, D.C., 554-1404; or, tollfree 800-424-9065).

## Information Gathering and Dissemination

### Chemical Substances Inventory

On June 1, 1979, the Agency published the initial Chemical Substances Inventory (under section 8(b) of TSCA) which lists over 44,000 commercial chemical substances manufactured or imported in the U.S. On October 31, a supplement was issued, adding 3,000 more chemicals to this list. Processors and distributors of chemical substances had until December 31, 1979, to review the list for completeness and add any chemicals not listed which have been processed for a commercial purpose since January 1, 1975. A revised chemical substances inventory will be published in 1980.

In the process of preparing this inventory, the Agency also collected information on where these chemicals are manufactured and in what quantities. This information will be useful to EPA when it begins to select chemical substances for attention and action under TSCA.

## Data Collection, Dissemination, and Utilization

Under the provisions of section 10(b), EPA is proceeding to develop computer-based data systems which will enable the Agency to make effective use of the data submitted under TSCA. The Chemicals in Commerce Information System (CICIS) will allow the Agency to process and analyze data submitted in support of the Inventory, health and safety studies, premanufacture notification, and specific chemical regulations. Portions of CICIS became operational in late 1979. There will be full public access to all nonconfidential information on file in this system. A comprehensive Chemical Substances Information Network (CSIN) currently under development in cooperation with other Federal agencies will link various toxic substances data systems, including CICIS, to further facilitate the exchange of information. The Agency is taking steps to assure that all confidential business information on file in these systems will be strictly protected.

## Section 8--Reporting and Retention of Information

Section 8 of TSCA empowers EPA to obtain various kinds of information from chemical manufacturers, processors, and distributors. Under this section, the Agency is currently developing a set of recordkeeping and reporting regulations and expects to publish a number of proposed rules in 1980. These include a set of reporting rules under section 8(a) to support the Agency's comprehensive risk assessment of chemicals in commerce as well as to obtain data needed by other EPA programs or other Federal agencies. Another section 8(a) rule to be proposed in early 1980 will require reports on the composition of selected chemical trade name products.

Under section 8(c) the Agency published a proposed rule (June 1980) requiring manufacturers, processors, and distributors to maintain and submit information on adverse health and environmental effects of certain chemicals.

Section 8(d) empowers the Agency to require the submission of health and safety studies. Final rules promulgated under this section in July 1978 (43 FR 30984) were revoked in January 1979 (44 FR 6099). A new proposed rule exercising essentially the same authority a the revoked rule will be published in early 1980.

Under section 8(e), chemical manufacturers, processors, and distributors are required to report information documenting that a chemical substance or mixture presents a substantial risk or injury to health or the environment. To date, the Agency has received over 300 such notices, many of which contained information already well known or not significant. Several notices, however, have prompted further investigation by EPA or referral to other Federal agencies.

## Testing

Under section 4 of TSCA, EPA is developing rules requiring manufacturers, processors, and distributors of chemical substances to perform tests to determine the chemical's effect on human health and the environment. The Act requires that these test rules include standards specifying the procedures to be used in conducting required tests. Testing standards will be directed at specific characteristics and health effects, as well as environmental fate, persistence, and ecological effects.

On May 9, 1979, (44 FR 2733) the Agency proposed test standards for oncogenic (tumor forming), non-oncogenic chronic, and combined oncogenic and non-oncogenic chronic health effects. In addition, on July 26, 1979, (44 FR 44054) test standards were proposed for mutagenic effects, teratogenic and reproductive effects, general metabolism testing, and a variety of acute and subchronic toxicity studies. Good laboratory practices for each of these health effects testing standards were also proposed.

The work on test standards for a number of environmental toxicity and chemical fate characteristics, along with good laboratory practices for each, is proceeding rapidly. These standards will be proposed in 1980.

## Chemical Control

Under TSCA, the Administrator of EPA may prohibit or limit the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture if he finds that these activities or any combination of them presents or will present an unreasonable risk of injury to health or the environment. A number of chemical control actions have been initiated to date.

### Polychlorinated Biphenyls (PCBs)

On May 31, 1979, the final ban rule for polychlorinated biphenyls (PCBs) was issued. This rule, with a few specified exceptions, banned the manufacture, processing, distribution, and non-totally enclosed use of PCBs after July 1 of this year. The May 1979 rule also reduced the minimum PCB concentration of materials covered by the ban, and the 1978 marking and disposal rules, from 500 ppm to 50 ppm.

Due to the mounting evidence that exposure to asbestos fibers can cause lung damage and several types of cancer, EPA initiated a nationwide voluntary program in March 1979 to help States and school districts identify schools where deteriorating asbestos-containing material should be removed or sealed. Subsequently, it was decided to develop regulations to protect against this risk and an advanced notice of proposed rulemaking (ANPRM) was issued on September 20, 1979, (44 FR 54676).

### Chlorofluorocarbons (CFCs)

In March 1978 the Agency, along with the Food and Drug Administration and the Consumer Product Safety Commission, banned the use of chlorofluorocarbons (CFCs) in aerosol products (43 FR 11301). During 1979, EPA continued to investigate the feasibility of controlling nonaerosol applications of CFCs and, in addition, has encouraged other nations to take actions to control CFC emissions.

## Premanufacture Notification

Under section 5 of the Act, any person who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to EPA at least 90 days prior to its manufacture or importation. A "new chemical substance" is one not included on the Inventory of existing substances published under section 8(b) on June 1, 1979. The requirements of section 5 became effective July 1, 1979.

On January 10, 1979, EPA proposed rules and notice forms for the premanufacture notification (PMN) program in the Federal Register. Subsequently, due to the number and nature of comments received on these proposed rules, the Agency decided to repropose portions of the January 10 notice. The Agency published this reproposal in the Federal Register on October 16, 1979, (44 FR 59764), allowed a 45-day comment period, and held public meetings with representatives of the chemical industry, public interest groups, organized labor, and others upon request. After EPA reviews the public record, the Agency expects to promulgate the rules and forms during mid-1980.

Over the coming months EPA will undertake a major rulemaking effort to develop significant new use rules both for selected new substances after their production begins as well as for certain existing substances.

# OFFICE OF PESTICIDE PROGRAMS

Environmental Protection Agency
401 M St. SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

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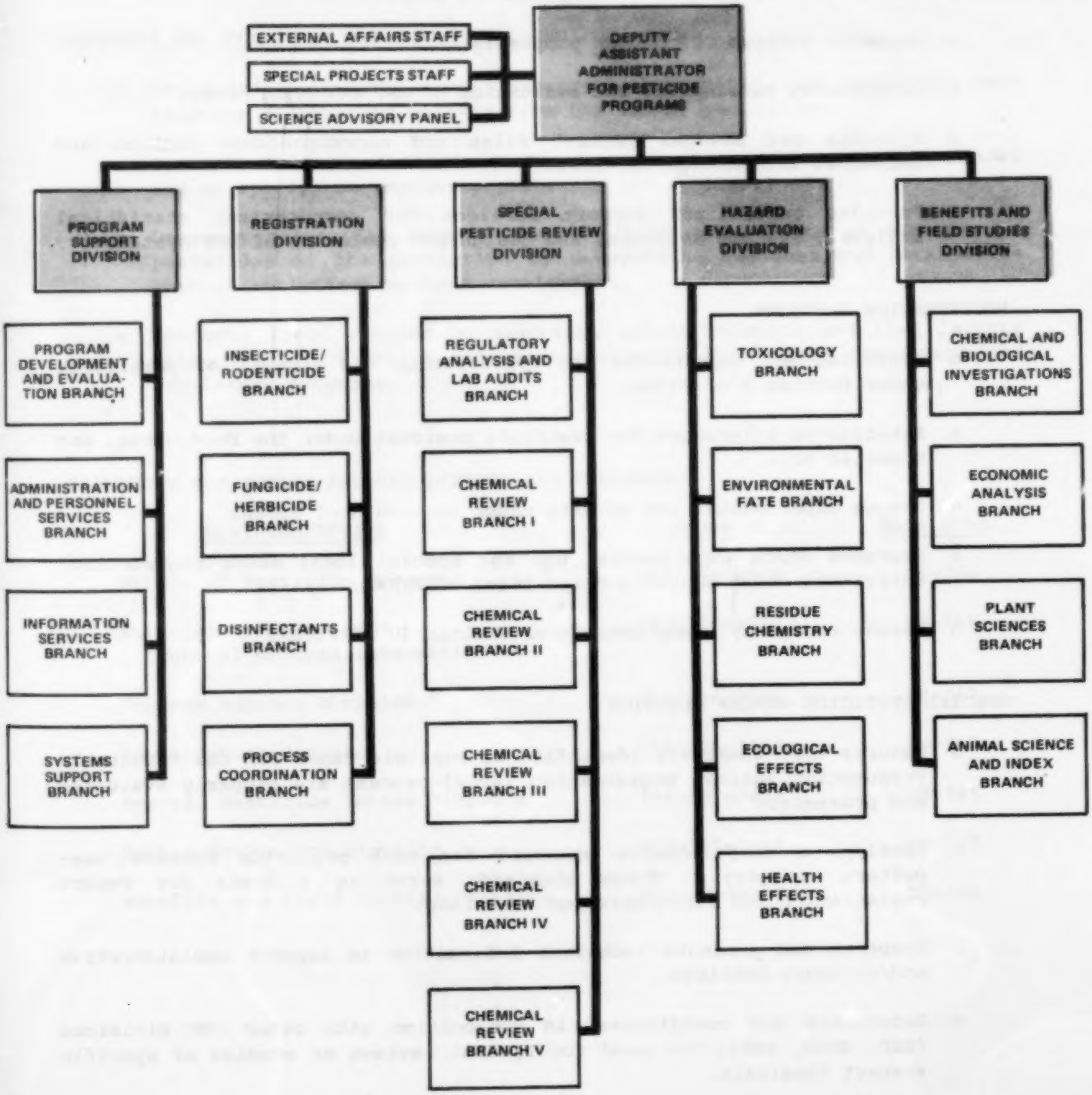
The Office of Pesticide Programs is responsible for implementing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). As such, the Office coordinates all Agency programs concerning pesticide management and regulation, including the establishment of tolerance levels for pesticide residues which occur in or on food; the registration and reregistration of pesticides; the monitoring of pesticide levels in food, humans, and nontarget fish and wildlife; and the preparation of guidelines and standards for products in the development of more effective pesticide control programs. In addition, the Office provides policy direction to technical and manpower training activities in the pesticide area; develops research needs and monitoring requirements for the pesticide program; reviews impact statements dealing with pesticides; and carries out assigned international activities.

# ENVIRONMENTAL PROTECTION AGENCY
# OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
# OFFICE OF PESTICIDE PROGRAMS
## ORGANIZATIONAL CHART



EXTERNAL AFFAIRS STAFF
SPECIAL PROJECTS STAFF
SCIENCE ADVISORY PANEL
DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDE PROGRAMS
PROGRAM SUPPORT DIVISION
REGISTRATION DIVISION
SPECIAL PESTICIDE REVIEW DIVISION
HAZARD EVALUATION DIVISION
BENEFITS AND FIELD STUDIES DIVISION
PROGRAM DEVELOPMENT AND EVALUATION BRANCH
ADMINISTRATION AND PERSONNEL SERVICES BRANCH
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# ORGANIZATION

## PROGRAM SUPPORT DIVISION (PSD)

- Assists in OPP program development and evaluation.
- Prepares various OPP budget proposals.
- Coordinates development and evaluation of OPP research needs.
- Provides and manages central files and correspondence control and technical information services.
- Provides centralized support services for computerized statistical analyses, systems analyses, and design and operation of ADP systems.

## REGISTRATION DIVISION

- Evaluates and coordinates the registration and renewal of pesticides under Section 3 of FIFRA.
- Establishes tolerances for pesticide residues under the Food, Drug, and Cosmetic Act.
- Issues experimental use permits under Section 5 of FIFRA.
- Oversees State experimental use and special local needs registration activities under Sections 5 and 24(c) of FIFRA.
- Issues emergency exemptions under Section 18 of FIFRA.

## SPECIAL PESTICIDE REVIEW DIVISION

- Assures that chemicals identified as possible cases for the Rebuttable Presumption Against Registration (RPAR) process are properly evaluated and processed.
- Develops a comprehensive standard for each pesticide chemical/use-pattern category. These standards serve as a basis for future registration and reregistration decisions.
- Prepares and presents technical information to support administrative and/or court hearings.
- Determines and coordinates, in conjunction with other OPP Divisions (HED, BFSD, PSD), the need for special reviews or studies of specific suspect chemicals.

## HAZARD EVALUATION DIVISION (HED)

- Reviews, evaluates, and validates all data submitted on the toxicological and adverse effects on humans, domestic animals, fish and wildlife, and other biological species resulting from the use of pesticides.
- Performs risk assessments on proposed and existing pesticide uses.
- Provides scientific expertise on adverse effects of pesticides to other Agency programs and other Federal Agencies.

## BENEFITS AND FIELD STUDIES DIVISION (BFSD)

- Retrieves, validates, and interprets scientific and technical data relative to benefits derived from the use of pesticides.
- Conducts economic analyses on the impacts of cancellations/suspensions and on special or emergency pesticide use applications.
- Develops scientific data on the magnitude and effects of exposure to pesticides on the population by determining residues and metabolites through analytical methods development.
- Conducts field studies to associate actual exposure and risk factors with identified health effects of uses by the hazard assessment and regulatory programs.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Office of Pesticide Programs | 202-755-8033 | TS-766 |
| External Affairs Staff (general program information) | 202-755-8020 | TS-766 |
| Program Support Division | 202-426-9033 | TS-757 |
| Registration Division | 202-426-2451 | TS-767 |
| Special Pesticide Review Division | 703-557-7438 | TS-791 |
| Hazard Evaluation Division | 703-557-7351 | TS-769 |
| Benefits and Field Studies Division | 202-472-9300 | TS-768 |

# STATUTORY AUTHORITIES

## The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Public Law 92-516 7 U.S.C. § 136

Agricultural chemicals have been regulated by the Federal Government since the turn of the century. The present law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), was passed in 1947 and significantly amended several times since then, most recently in 1978. It was administered by the Department of Agriculture until 1970 when jurisdiction was transferred to the Environmental Protection Agency. The purpose of the Act is to control the use of pesticides to safeguard the health of the public and to prevent adverse effects on the environment.

### Key Sections of Act--Toxics Focus

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| sec. 2 | Defines terms related to pesticide production and use. |
| sec. 3 | Requires registration, reregistration, and classification of pesticides; authorizes conditional registration pending full data development in certain circumstances. |
| sec. 3(g) | Requires that pesticides leaving postharvest residues on food or field crops be given priority in the reregistration process. |
| sec. 4 | Authorizes EPA to prescribe standards for the certification of pesticide applicators and use of restricted use pesticides. |
| sec. 4(c) | Encourages distribution of instructional materials on integrated pest management (IPM). |
| sec. 5 | Provides for issuance of experimental use permits for new pesticides so that data required for registration may be gathered. |
| sec. 6(a) | Requires cancellation of registration after 5 years unless a request for continuance is submitted and approved. |
| sec. 6(b) | Authorizes EPA to cancel pesticides that cause unreasonable adverse effects on the environment. |

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| sec. 6(c) | Authorizes EPA to suspend the registration of a pesticide immediately to prevent an "imminent hazard." |
| sec. 7 | Requires registration of pesticide production facilities. |
| sec. 8(a) | Authorizes EPA to require that producers maintain books and records. |
| sec. 8(b) | Authorizes EPA to conduct in-plant inspections of books and records. |
| sec. 9 | Authorizes EPA to make in-plant inspections and obtain samples of pesticides, devices, packages, and labels for purposes of enforcement. |
| sec. 9(b) | Authorizes EPA to obtain and execute warrants. |
| sec. 9(c) | Requires certification of facts to the Attorney General by EPA for enforcement purposes. |
| sec. 10 | Provides for protection of trade secrets. |
| sec. 11 | Exempts private pesticide applicators from recordkeeping. |
| sec. 12 | Defines unlawful acts. |
| sec. 13 | Authorizes the Administrator to issue a 'stop sale, use, or removal' order for pesticides or devices which are in violation of any provisions of this Act. |
| sec. 14 | Details the civil and criminal penalties for violation of the provisions of this Act. |
| sec. 15 | Authorizes the Administrator to issue an indemnity payment under certain conditions. |
| sec. 16(b) | Allows persons to obtain judicial review on EPA actions against pesticides. |
| sec. 17(a) | Permits export of pesticides if in compliance with various labeling requirements of the Act. Requires a purchaser acknowledgment statement prior to export of an unregistered pesticide. |
| sec. 17(b) | Requires EPA to furnish notices of registration, cancellation, or suspension to foreign governments. |
| sec. 17(c) | Details procedures to follow regarding the import of pesticides. |
| sec. 18 | Authorizes emergency exemptions from provisions of the Act to Federal agencies and States to meet pest control emergencies, and requires consultation with affected Governor(s). |

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| sec. 19 | Authorizes EPA to establish procedures and regulations for the safe disposal and/or storage of pesticides and pesticide containers and to accept for disposal, upon request of the owner, any cancelled pesticides. |
| sec. 20 | Authorizes research and monitoring activities. |
| sec. 23 | Authorizes cooperative agreements with States and Indian tribes for enforcement and training of certified applicators. |
| sec. 24 | Authorizes State registration of pesticides, consistent with section 3, for use within the State to meet special local needs. |
| sec. 26 | Gives States primary responsibility for enforcement of the Act. |
| sec. 28 | Requires EPA to cooperate with the Department of Agriculture to identify pests and develop controls. |

### Regulatory Options Available Under Statute

- Require registration of pesticides
- Prescribe standards for certification of applicators
- Classification for general or restricted use
- Cancel registration
- Suspension of registration in imminent hazard circumstances and cancellation upon final determination by the Administrator
- Regulate storage and disposal of pesticides and pesticide containers (see also, Resource Conservation and Recovery Act)
- Seizure of unregistered, etc., pesticides

## The Federal Food, Drug, and Cosmetic Act (FFDCA)*

### Public Law 69 21 U.S.C. §§ 301-392

The Federal Food, Drug, and Cosmetic Act was passed in 1938 to replace the earlier Food and Drug Act of 1906. National legislation in this area became necessary as competition between food manufacturers for sales profits led to the debasement and/or the mislabeling of foods and other products. However, weaknesses in the 1906 Act were pointed out when 107 deaths resulted from "Elixir of Sulfanilamide." This incident called attention to the need for premarket testing of new drugs. The 1938 Act addressed these needs and brought cosmetics under FDA regulation as well.

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*Note: The Food and Drug Administration (FDA) is responsible for implementing most of the provisions of this statute and for enforcing tolerance levels set by EPA. FDA is covered in another section of this publication.

The purposes of the Food, Drug, and Cosmetic Act are to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that medical devices are safe and effective for their intended uses, including drugs used in medicated feeds for animals; that cosmetics are safe and properly labeled; and that packaging and labeling of these products is truthful and informative.

Since 1938, the Act has been amended several times. Among the more prominent amendments have been the Food Additives Amendment of 1958, which prohibits the introduction of new food additives until the manufacturer can prove their safety; the Color Additive Amendments of 1960 which gave FDA authority to control the conditions for safe use of a color additive, including the amount of color used in a product; and the Drug Amendments of 1962, which required, among other things, that all drugs be proven effective as well as safe.

EPA has the authority, under Sections 406, 408, and 409 of this Act, to establish tolerance levels for pesticide residues in food. A tolerance is the legal maximum residue of a pesticide chemical allowed to remain in or on a food. Under the FFDCA, if the residue exceeds the tolerance level then the food is "adulterated" and is subject to seizure by the Food and Drug Administration (FDA). The tolerance requirements of the FFDCA are also applicable to imported food, whether or not the pesticide is registered for use in the United States.

Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 406 | Permits the establishment of tolerances for poisonous or deleterious substances including pesticides which (1) are required in the production of food or (2) otherwise cannot be avoided by good manufacturing practices. |
| sec. 408 | Authorizes the establishment of tolerances for pesticides used in or on food or feed. |
| sec. 409 | Authorizes the establishment of tolerances for pesticides which are food additives. (A pesticide is a food additive when (1) it is carried over from use on a raw agricultural commodity and after processing remains in the processed food at a concentration higher than originally found in the raw agricultural commodity, or (2) it is added to a processed food.) |

Regulatory Options Available Under Statute

- Set tolerances/revoke tolerances
- Deem products to be misbranded
- Establish standards or conditions
- Require registration or certification

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 199 of this publication.

## EXISTING REGULATIONS

Federal Insecticide, Fungicide, and Rodenticide Act 40 CFR 160-180

# TOXICS-RELATED ACTIVITIES

## Registration of Pesticides

Registration or pre-market clearance of pesticides involves a comprehensive review of human and environmental risks and a limited review of benefits data submitted by industry. Risk is often quantified in terms of the number of or probability of certain health and environmental effects, while benefits are usually expressed in dollar valuations of such effects as increased crop yields, lower food costs, reduced chance of disease, or the cost savings with respect to the use of alternative control measures.

The Federal Pesticide Act of 1978, which amended FIFRA, authorized a program for EPA to grant conditional registrations. Under this program, EPA is able to process applications of new products which are similar to ones already registered and new uses of old chemicals if sufficient information is available to evaluate the unique hazards posed by new uses. New chemicals are also eligible for conditional registration if EPA determines that the public interest would be served by registration, and if unreasonable risks will not be incurred during the period required to complete and submit additional studies.

Central to the conditional registration program is incremental risk assessment. The amended FIFRA requires the Agency to focus its attention only on the increased risks or incremental risks resulting from the registration of old pesticides and new uses of old pesticides. Specifically, conditional registration of both identical and substantially similar products and uses and new uses is authorized only if the new use or product will not significantly increase the risk of unreasonable adverse effects on the environment.

In Fiscal Year 1979 the registration program continued to give top priority to environmentally safe and innovative compounds and technologies, such as biorational compounds and other alternative means of pest management. During Fiscal Year 1979, the Registration Program received 59 new active ingredients, 1,772 previously registered active ingredients, and 26,671 amendments and supplemental registration applications. Out of the 59 new chemical registration submissions received, 23 were approved. This represents a 180 percent increase in the approval of new chemical registrations compared to Fiscal Year 1978. The approval rate for old chemicals, amendments, and supplemental registrations remained approximately the same for Fiscal Year 1979.

## Pesticide Tolerances

Under the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA), the Agency is required to establish tolerance levels and exemptions from the requirements for a tolerance. These tolerance levels protect the public health while giving appropriate consideration to the production of an adequate, wholesome, and economical food supply. Determination of tolerances involves careful review and evaluation of residue chemistry and toxicology safety data to ensure that maximum residue levels likely to be found in food or feed are safe for human consumption. Included in this consideration is the cumulative effect of the respective pesticide and related substances with the same physiological activity.

## Pesticide Use Management

The Regional or Use Management Program has been established to assist States in handling special pesticide incidents (kills, fires, etc.) and registration needs and to certify applicators to purchase and use restricted use pesticides. OPP's Use Management Program provides technical assistance, guidance, and policy to the Regions, States, and local governments concerning pesticide issues and Agency programs and decisions.

As part of the Public Outreach Program, the Use Management staff in Fiscal Year 1979 responded to more than 10,000 external requests for pesticide-related information, such as training materials, certified applicator standards, registration, and use of pesticide information. In addition they issued 52 Weekly OPP Operational Reports to the Regions, States, and other external groups, developed 3 certification and training manuals, and planned and coordinated the second National Certification and Training Meeting held in Fiscal Year 1979 in Dallas, Texas.

## Registration (Generic) Standards

The Registration Standards System, a new approach to reregistration sanctioned by the 1978 amendments, will streamline the reregistration process. Instead of reregistering each of the 41,000 products on a case-by-case basis, the Agency is developing comprehensive registration standards for each active ingredient common to numerous pesticide products. Out of the 41,000 registered pesticide products, EPA will be concentrating its effort on the review of approximately 500 chemicals (active ingredients) representing the major pesticide chemicals produced.

The development of a registration standard is divided into five phases: (1) Phase I--Data gathering and preparation, (2) Phase II--Scientific review, (3) Phase III--Identification and analysis of regulatory options, (4) Phase IV--Regulatory standard drafting and publication, and (5) Phase V--Integration of comments and preparation of the revised standard.

For every pesticide chemical and its formulations, safety criteria will be set, to which registrants must adhere, in order to register and reregister products. An intensive risk/benefit review will be conducted only for those chemicals which meet the "unreasonable adverse effects" criteria. All other chemicals will require a risk analysis only. In addition, standards for registration will state tolerable levels of exposure for food consumers, field workers, applicators, and other persons and organisms unintentionally exposed to pesticides, and will facilitate reassessments of tolerances to minimize pesticide exposure of workers, applicators, and others.

## Rebuttable Presumption Against Registration (RPAR)

The RPAR process is an intensive risk/benefit review of pesticide chemicals suspected of causing unreasonable adverse health or environmental impact. OPP employees, with the support of other EPA offices and Federal agencies, develop recommendations for a regulatory position with regard to the registration, suspension, cancellation, restriction on uses, or removal of pesticides containing the chemical under review.

The RPAR process begins when a suspected pesticide chemical is referred to the Special Pesticide Review Division for consideration. Before this chemical can be accepted as an RPAR candidate, data supporting the statement of risk must be scientifically validated. After acceptance as an RPAR candidate, a project team is named and a comprehensive literature search is initiated for the pre-RPAR chemical. The first part of the RPAR process focuses on the development of a risk assessment, followed by a publication of the Agency's position on the pre-RPAR chemical in the Federal Register. During the comment period, the public, manufacturers, and users are given an opportunity to offer evidence in rebuttal or in support of the presumption against registration.

If the rebuttal comments are unsuccessful, the project team develops a risk/benefit analysis for each significant use and each regulatory option of the RPAR chemical. Representing the proposed Agency decision, the second Position Document is published in the Federal Register followed by a second public comment period. The tentative Agency decision and supporting data are reviewed by USDA and the EPA Scientific Advisory Panel (SAP). Their recommendations and appropriate public comments are incorporated into the final regulatory document and forwarded to the Assistant Administrator, Office of Pesticides and Toxic Substances, for approval. After this comprehensive review and sign-off process is completed, EPA publishes the final decision in the Federal Register. The Agency may decide to register or reregister or restrict all or some of the uses of the pesticide.

In 1979, OPP completed proposed decisions for nine RPAR chemicals and proceedings for five chemicals. Some of the more important RPAR decisions included the following chemicals: Chlorobenzilate, Edrin, DBCP, Trifuralin, Dimilin, Pronamide, BAAM (Amitraz), 2,4,5-T and Silvex.

## Laboratory Audit Program

The Office of Pesticide Programs established a Laboratory Audit Program because of indications that there were defects in basic studies used to support pesticide registrations. The data validation process is critical to all the basic regulatory programs in OPP, including removal or restriction of hazardous pesticides and development of registration standards.

In cooperation with the Federal Drug Administration and EPA's Office of Enforcement, OPP personnel have been managing systematic audits of independent testing laboratories which generate toxicology data in support of the registration of pesticides. After conducting laboratory audits, OPP audit personnel recommend appropriate regulatory and/or judicial action.

During Fiscal Year 1979, OPP personnel conducted 33 on-site data audits and 190 reviews of registrant validations of possibly faulty lab data. The lab audit process identified several new suspect chemicals and four labs which had significant problems.

In Fiscal Year 1979, OPP also developed a prototype standard for the chemical metolachlor which was designed to give industry and the public an example of a standard and to solicit their comments concerning the standard. It should be noted that this prototype standard is not the Agency's final regulatory position on metolachlor but rather a model that will enable OPP to improve future standards development.

Other major accomplishments included the completion of an Advanced Notice of Proposed Rulemaking (ANPRM), establishing the Agency's preferred method for conducting analyses for registration standards development as well as a number of miscellaneous changes to the existing registration regulations. The ANPRM addresses the organization, preparation, content, and maintenance of a standard as well as the issue of its legal status and the order of development of standards.

## Special Registration of Pesticides

The Special Registration Program was established to respond promptly and effectively to unexpected and temporary health and agricultural exigencies and to support State and local governments in registering pesticides for local or State use. Under the Special Registration Program, OPP issues emergency exemptions under Section 18 of the FIFRA, Experimental Use Permits (EUPs) under Section 5, and temporary tolerances to establish safe levels of pesticide residues in food and feed from pesticide use for experimental purposes.* OPP also monitors Section 24(c) registrations by States, and minor use registrations or minor use/specialty crop petitions for tolerance submitted by public interest user-oriented groups, such as the Inter-Regional Project No. 4 (IR-4) based at Rutgers University.

Under the Special Registration Program, emergency exemptions may be granted to State or Federal agencies, authorizing pesticides to be used for purposes not included on registered labeling. Emergency situations which are deemed to justify granting of an emergency exemption must meet the following requirements: (1) A pest outbreak has occurred or is about to occur and no pesticide registered for the particular use, or alternative method of control, is available to eradicate or control the pest, (2) significant economic or health problems will occur without the use of the pesticide, and (3) the time available from discovery or prediction of the pest outbreak is insufficient for a pesticide to be registered for the particular use. In determining whether an emergency condition exists, OPP scientists and product managers carefully evaluate the benefits as well as the human and environmental risks associated with the use of such pesticides.

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*Temporary tolerances submitted in support of EUPs allow for continuing pesticide research on agricultural crops used for feed or food.

Because of the extremely broad authority provided under Section 18 of FIFRA regarding emergencies, these exemptions may include use of pesticides on crops for which no tolerances have been established (approximately 95 percent fall into this category) and, in some cases, pesticides which have been canceled for the proposed use. Granting of emergency exemptions results in reduced annual crop losses amounting to millions of dollars each year. The exemptions have spared growers catastrophic economic losses and have prevented the loss of millions of pounds of valuable food commodities. Emergency exemptions also have been granted for various public health emergencies, such as rabies and plague; quarantine situations, such as witchweed and citrus black fly; and for protection of endangered species.

Experimental Use Permits (EUPs) allow registrants to perform large-scale experimentation needed for the development of data for new pesticides or new uses of currently registered pesticides. Data generated from the issuance of EUPs are used to evaluate the potential hazards to man and the environment from the use of these pesticides. In cases where crops will not be destroyed after the experimental program is ended, a temporary tolerance for a safe residue level on the food or feed commodity must be established by the Agency before the EUP is issued. The Office of Pesticide Programs issues EUPs and establishes temporary tolerances based upon a case-by-case scientific determination of the human and environmental risks and benefits associated with the use of a particular pesticide.

The Special Registration Program also includes approval or disapproval of States registrations of pesticides that are distributed and used only within a particular registering State. In conjunction with the State registration overview authority, OPP monitors the issuance of experimental use permits that are needed to support subsequent State registrations.

# *OFFICE OF WATER AND WASTE MANAGEMENT*

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

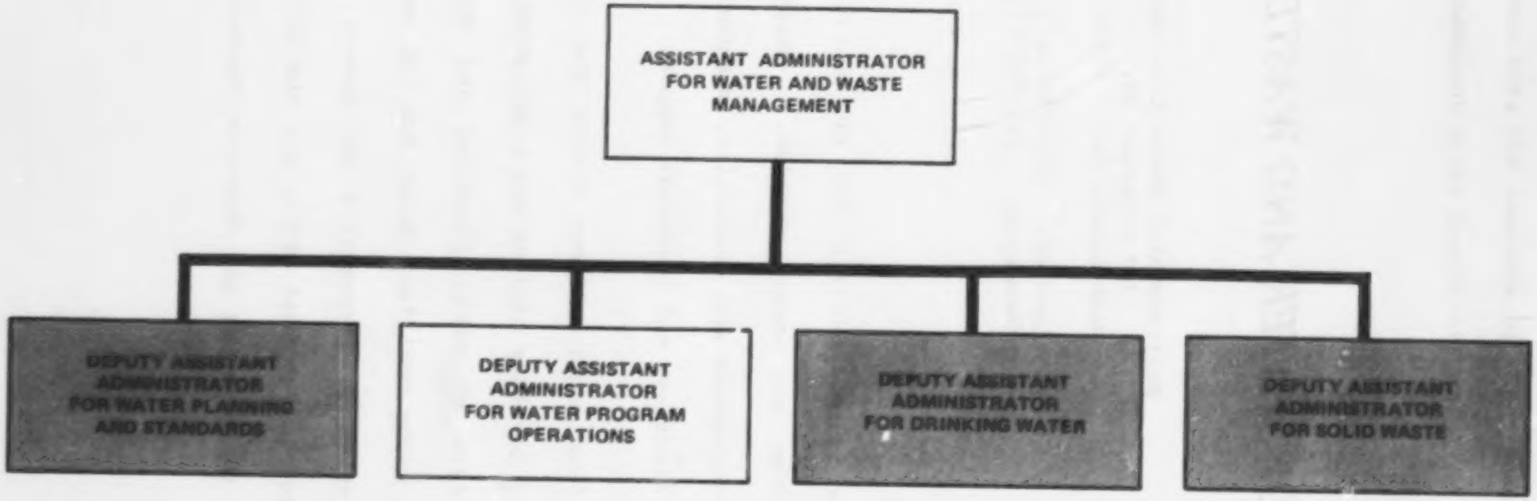
This Office is responsible for EPA activities pertaining to the management of water and waste programs. These responsibilities include program policy development and evaluation, standards development and program policy guidance, overview, and technical support.

There are four major offices within the Office of Water and Waste Management. Three of those offices are highlighted in this publication. They include the Office of Water Planning and Standards which has major responsibilities under the Clean Water Act (as amended 1977); the Office of Drinking Water which is responsible for Agency activities under the Safe Drinking Water Act (as amended 1977); and the Office of Solid Waste which is responsible for implementing the Resource Recovery and Conservation Act of 1976.

# ENVIRONMENTAL PROTECTION AGENCY

# OFFICE OF WATER AND WASTE MANAGEMENT

## ORGANIZATIONAL CHART*


ASSISTANT ADMINISTRATOR FOR WATER AND WASTE MANAGEMENT
DEPUTY ASSISTANT ADMINISTRATOR FOR WATER PLANNING AND STANDARDS
DEPUTY ASSISTANT ADMINISTRATOR FOR WATER PROGRAM OPERATIONS
DEPUTY ASSISTANT ADMINISTRATOR FOR DRINKING WATER
DEPUTY ASSISTANT ADMINISTRATOR FOR SOLID WASTE

*NOTE: A partial organizational chart is shown to highlight (in gray) those components of the Office of Water and Waste Management ordinarily involved in toxic substances activities.

# OFFICE OF WATER PLANNING AND STANDARDS

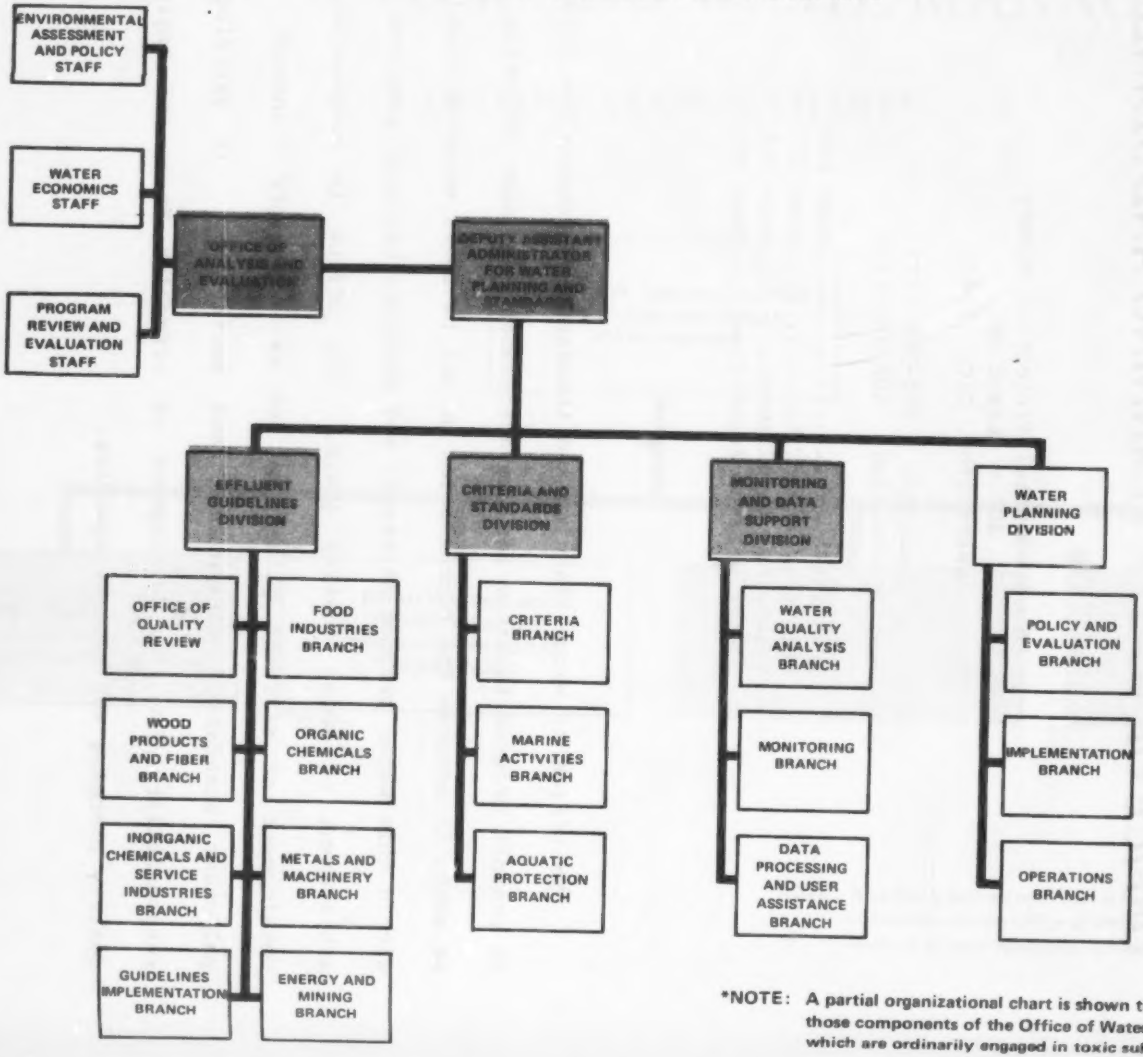
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

Organization..................page 249
Statutory Authority...........page 252
Regulatory Development........page 254
Toxics-Related Activities.....page 255

The Office of Water Planning and Standards is responsible for developing an overall program strategy for the achievement of water pollution abatement. As such, it assures the coordination of all national water-related activities within this water program strategy, and monitors national progress toward the achievement of water quality goals. The Office is responsible for the development of effluent guidelines and water quality standards, and other pollutant standards, regulations, and guidelines. It exercises overall responsibility for the development of effective State and regional water quality planning and control agencies.

# ENVIRONMENTAL PROTECTION AGENCY
## OFFICE OF WATER AND WASTE MANAGEMENT
# OFFICE OF WATER PLANNING AND STANDARDS
## ORGANIZATIONAL CHART*



ENVIRONMENTAL ASSESSMENT AND POLICY STAFF
WATER ECONOMICS STAFF
PROGRAM REVIEW AND EVALUATION STAFF
OFFICE OF ANALYSIS AND EVALUATION
DEPUTY ASSISTANT ADMINISTRATOR FOR WATER PLANNING AND STANDARDS
EFFLUENT GUIDELINES DIVISION
OFFICE OF QUALITY REVIEW
FOOD INDUSTRIES BRANCH
WOOD PRODUCTS AND FIBER BRANCH
ORGANIC CHEMICALS BRANCH
INORGANIC CHEMICALS AND SERVICE INDUSTRIES BRANCH
METALS AND MACHINERY BRANCH
GUIDELINES IMPLEMENTATION BRANCH
ENERGY AND MINING BRANCH
CRITERIA AND STANDARDS DIVISION
CRITERIA BRANCH
MARINE ACTIVITIES BRANCH
AQUATIC PROTECTION BRANCH
MONITORING AND DATA SUPPORT DIVISION
WATER QUALITY ANALYSIS BRANCH
MONITORING BRANCH
DATA PROCESSING AND USER ASSISTANCE BRANCH
WATER PLANNING DIVISION
POLICY AND EVALUATION BRANCH
IMPLEMENTATION BRANCH
OPERATIONS BRANCH

*NOTE: A partial organizational chart is shown to highlight (in gray) those components of the Office of Water Planning and Standards which are ordinarily engaged in toxic substances activities.

# ORGANIZATION

## OFFICE OF ANALYSIS AND EVALUATION

- Develops a national water pollution abatement and prevention plan which sets forth the framework for implementing Agency water-related activities in an integrated, coordinated, and timely manner.
- Performs economic analyses and prepares inflationary impact statements to support regulations developed by the Office of Water Planning and Standards for the abatement and control of point and nonpoint sources of pollution, and for monitoring, planning activities, and other regulatory programs of that Office.
- Provides statistical support and expert review of all regulations developed by the Office of Water Planning and Standards, and those of other offices upon request. Also provides statistical and operations research assistance to the monitoring activity and the criteria development process.
- Integrates the health, economic, and technical studies prepared to implement EPA's toxics control program for water discharges into a coherent framework for decisions by top management on the level of control and the regulatory mechanism for control.
- Conducts national level coordination with other Federal agencies to secure their participation, support, and agreement with strategy and regulations, and presents results of analyses to high-level representatives of industry, the Federal Government, State and local governments, and public interest groups.

## EFFLUENT GUIDELINES DIVISION

- Develops industrial point source effluent limitations and pretreatment standards for controlling the discharge of toxic compounds and traditional pollutants into the Nation's waterways.
- Provides engineering and analytical technical expertise in defining the most appropriate technologies for pollution control and developing methods to sample and determine the presence and concentration of toxic materials in wastewater media and sludges.
- Assists in refining sludge disposal regulations under the Resource Conservation and Recovery Act.

- Conducts indepth technical studies relating to innovative and alternative treatment technologies and recycling and reuse of wastewater to minimize the overall discharge of all toxics into the environment.

- Conducts engineering analyses and data acquisition to evaluate the occurrence and impact of toxic pollutants in the raw waste and treated wastewaters and sludge streams discharged by industry.

## CRITERIA AND STANDARDS DIVISION

- Develops and revises water quality criteria, toxic effluent standards, and hazardous substance designations and regulations.

- Serves as an authoritative source of technical and scientific information on water quality criteria and standards, and on the effects of water pollutants on health and welfare.

- Develops and coordinates programs to correct water pollution problems in freshwater lakes and estuarine areas.

- Develops standards and guidelines for correction of water pollution problems resulting from such sources as dredge spoils, in-place toxicants, discharge from vessels, and aquaculture.

## MONITORING AND DATA SUPPORT DIVISION

- Develops strategies for toxic pollutant management on a pollutant-by-pollutant basis, a source-by-source basis, and an area-by-area basis. This involves collection, development, and analysis of toxic pollutant information including sources, uses, losses, ultimate fate, populations exposed, and risks associated with pollutants. It also involves collection, development, and analysis of data on industrial, municipal, and nonpoint source contributions of toxic pollutants to waters as well as data on their environmental and health implications.

- Manages EPA Regional and State water monitoring programs to identify and control toxic problems in areas where toxic controls greater than Best Available Technology (BAT) are required; reviews wasteload allocations conducted by the Regions and States for technical adequacy; reviews the water quality impacts of major advanced treatment (AWT) grant requests and provides final OWPS approval clearance for same.

- Serves as the Agency focal point for coordinating all ambient water monitoring activities conducted by EPA headquarters and Regional Offices.

- Provides all EPA program offices with reports assessing current trends in water quality, preparing the annual report on fish kill incidents resulting from both toxic and conventional pollutants and preparing public information documents detailing specific areas where pollution control efforts have resulted in significant environmental and/or public health.

- Obtains, reviews, stores, and analyzes ambient chemical, biological, ecological, and other data relating to toxic substances.

DIRECTORY FOR TOXICS-RELATED OFFICES/PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Office of Water Planning and Standards | 202-755-0402 | WH-551 |
| Office of Analysis and Evaluation | 202-755-6885 | WH-586 |
| Effluent Guidelines Division | 202-426-2576 | WH-552 |
| Criteria and Standards Division | 202-755-0100 | WH-585 |
| Monitoring and Data Support Division | 202-426-7764 | WH-553 |

*FTS numbers are the same.

# STATUTORY AUTHORITIES

## Clean Water Act

### Public Law 95-217   33 U.S.C. § 466

The Clean Water Act was passed in 1972 as the Federal Water Pollution Control Act. It represented a major reorientation of Federal efforts to achieve and maintain acceptable levels of water quality. The Act established a national goal of eliminating pollutant discharges into the Nation's waterways by 1985. In 1977, amendments to the Act helped shift attention to the control of toxic pollutants.

The purpose of the Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.

### Key Sections of Act--Toxics Focus

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|---|---|
| sec. 301 | Requires application of best available technology economically achievable to prevent discharge of toxic and nonconventional pollutants from point sources. |
| sec. 302 | Authorizes EPA to establish effluent limitations to attain or maintain water quality. |
| sec. 303 | Requires States to issue water quality standards and implementation plans. |
| sec. 304 | Requires EPA to publish:<br>(a) Water quality criteria information.<br>(b) Regulations providing guidelines for effluent limitations.<br>(c) Information on processes which eliminate or reduce the discharge of pollutants.<br>(d) Information on the degree of effluent reduction attainable through the application of secondary treatment.<br>(e) Regulations supplementing the effluent limitations in order to regulate toxic or hazardous pollutants. |

(f) Information identifying and evaluating nonpoint sources of pollution.

| | |
|---|---|
| sec. 307 | Requires EPA to publish a list of toxic pollutants or combinations of pollutants and to set effluent standards, pretreatment standards, and prohibitions for these. Gives EPA authority to set standards more stringent than Best Available Technology (BAT) if health and ecological impacts are not mitigated. |
| sec. 306 | Requires EPA to publish regulations establishing standards of performance for best available technologies to control discharge of pollutants. |
| sec. 308 | Sets forth conditions for inspections, monitoring, and entry. |
| sec. 310 | Enables EPA to act in conjunction with the Department of State and foreign governments to abate water pollution internationally. |
| sec. 311 | Authorizes EPA to regulate and act to mitigate the discharge of oil or hazardous substances into navigable waters. |
| sec. 401 | Requires facilities which discharge pollutants into water to be certified. |
| sec. 402 | Establishes conditions for issuance of permits to discharge into navigable waters. |
| sec. 404(a) | Authorizes the Army Corps of Engineers to issue permits for the discharge of dredged or fill material into waterways at specified disposal sites. |
| sec. 404(b) | Authorizes EPA to prohibit the specification of any area as a disposal site if the discharge of the dredged or fill material will have an adverse effect on people or the environment. |
| sec. 405(a) | Prohibits disposal of sludge without a permit. |
| sec. 405(b) | Allows regulations to be issued setting out guidelines for acceptable methods for disposal of sewage sludge. |
| sec. 504 | Authorizes EPA to act to stop or mitigate environmental discharges which present an imminent hazard. |

## Regulatory Options Available Under Statute

- Set guidelines and standards of performance for effluent limitations
- Require application of best available technology to control discharges
- Regulate discharges of hazardous substances
- Issue permits for discharge of dredged or fill material
- Prohibit discharge of hazardous dredged or fill material
- Regulate disposal of sludge

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

For a discussion of the regulatory process within the Environmental Protection Agency see page 199 of this publication.

## EXISTING REGULATIONS

| | |
|---|---|
| Clean Water Act | 40 CFR 400 |

# TOXICS-RELATED ACTIVITIES

The Office of Water Planning and Standards (OWPS) has three major toxics-related programs: developing nationally uniform industrial point source effluent limitations and pretreatment standards; developing water quality criteria; and managing ambient and end-of-pipe monitoring programs. These programs address a priority list of toxic chemicals established by a 1976 consent decree with Natural Resources Defense Council and codified in the 1977 Clean Water Act amendments. This list of 65 toxic substances includes some categories and families of substances, and has been refined by EPA to an initial list of 129 specific pollutants. EPA may add to or delete from this list by a rulemaking; to date one has been proposed.

## Effluent Limitations

The major Clean Water Act mechanism to control toxic chemical discharges is nationally uniform effluent limitations for industry categories. These are technology- and economic-based limitations on the discharge of specific process wastewater constituents.* OWPS is developing toxic effluent limitations for 129 consent decree toxic substances for 21 major industry categories. The first of these limitations was proposed in late 1979.

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*These limitations are implemented via the National Pollutions Discharge Elimination System (NPDES), which is managed by the Office of Water Enforcement. Under the NPDES program a permit incorporating any promulgated effluent limitation is written for every direct discharger to navigable waters.

## Water Quality Criteria

Water Quality Criteria have been proposed for each of the original 65 consent decree toxic substances; promulgation is expected in the fall of 1980. These Water Quality Criteria set ambient concentrations acceptable for aquatic organisms and human contact. These criteria are used, in conjunction with use designations, to establish State Water Quality Standards. Violations of Water Quality Standards may result in a requirement for water quality-based effluent controls more stringent than the existing technology- and economic-based limitations.

## Monitoring

The Office of Water Planning and Standards is responsible for developing monitoring strategies for the 129 priority toxic substances, both end-of-pipe and in-stream. This monitoring will identify water basins where controls more stringent than the technology-based limitations are required. This monitoring will also help determine the relative industrial, municipal and nonpoint source contributions of toxic pollutants to the Nation's waters.

# *OFFICE OF DRINKING WATER*

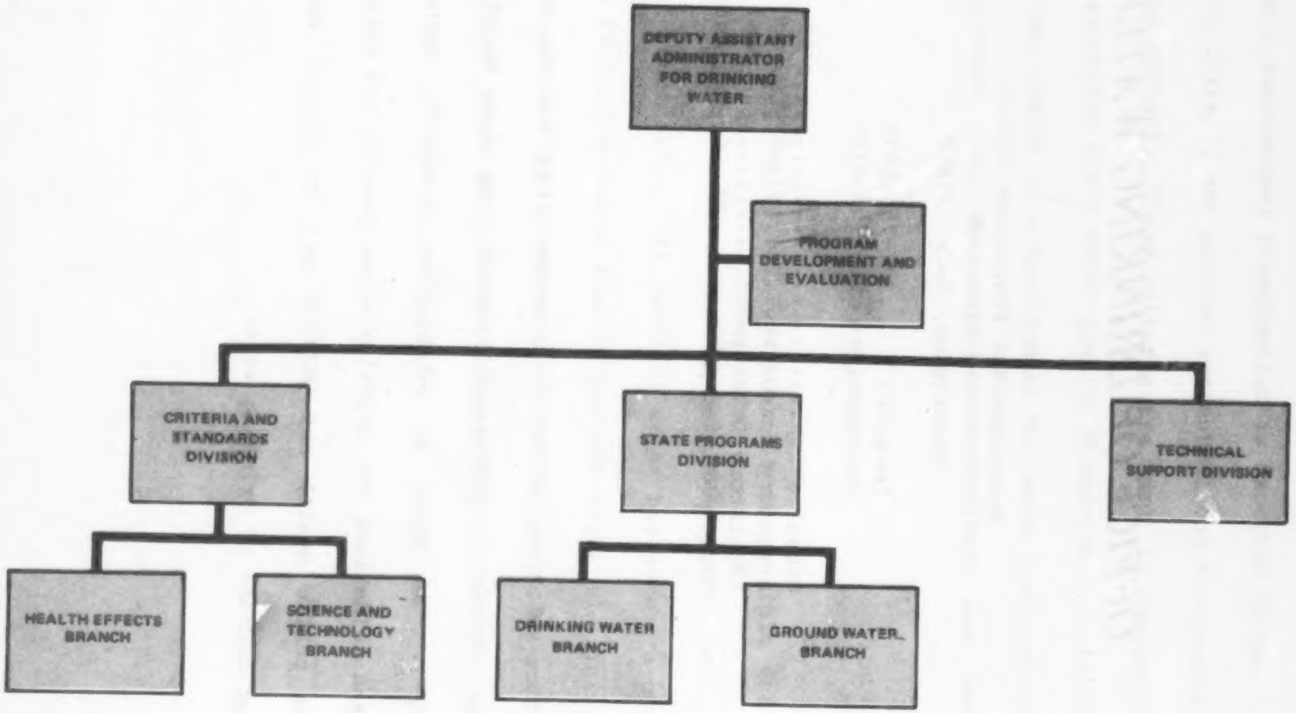
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

Organization....................page 00
Statutory Authority.............page 00
Regulatory Development..........page 00
Toxics-Related Activities........page 00

The Office of Drinking Water is responsible for the implementation and coordination of the program established by the Safe Drinking Water Act (as amended 1977). As such, it establishes standards, develops regulations, policies, and guidelines for drinking water quality and treatment requisite to protect the public health and welfare and to protect existing and future ground water sources of drinking water.

## ENVIRONMENTAL PROTECTION AGENCY
## OFFICE OF WATER AND WASTE MANAGEMENT
# OFFICE OF DRINKING WATER
## ORGANIZATIONAL CHART*


DEPUTY ASSISTANT ADMINISTRATOR FOR DRINKING WATER
PROGRAM DEVELOPMENT AND EVALUATION
CRITERIA AND STANDARDS DIVISION
STATE PROGRAMS DIVISION
TECHNICAL SUPPORT DIVISION
HEALTH EFFECTS BRANCH
SCIENCE AND TECHNOLOGY BRANCH
DRINKING WATER BRANCH
GROUND WATER BRANCH

*NOTE: A partial organization chart is shown here to highlight (in gray) those components of the Office of Drinking Water which are ordinarily involved in toxic substances activities.

# ORGANIZATION

## CRITERIA AND STANDARDS DIVISION

- Establishes and revises regulations and guidelines relating to primary and secondary drinking water standards.

### Health Effects Branch

- Develops health effects criteria for and manages development of the Primary Drinking Water Regulations.
- Proposes research and development work necessary to the establishment of Maximum Contaminant Levels (MCLs) as well as treatment requirements and criteria for health-related contaminants in drinking water.
- Defines research and health-effects needs.
- Maintains liaison with the Office of Research and Development of the EPA, and Federal and other agencies having health responsibilities.
- Provides toxicology opinions in emergency situations where a water supply might be affected.
- Reviews and provides informal advice with respect to direct and indirect additives to water and their potential health effects.

### Science and Technology Branch

- Develops the technical and scientific rationale for treatment regulations and maximum contaminant levels.
- Establishes and revises Secondary Drinking Water Regulations.
- Develops site selection, surveillance, and operation and maintenance regulations and guidelines.
- Develops appropriate standards and criteria for potable wastewater reuse.
- Initiates and monitors contracts and special studies in areas of the science and technology of water supply.
- Provides guidance and technical assistance to other government agencies with respect to water resources research and emergency water supply planning.

## STATE PROGRAMS DIVISION

- Develops and revises regulations and guidelines for State water supply programs and Underground Injection Control programs.
- Monitors regional implementation of State program aspects of the Safe Drinking Water Act.

### Drinking Water Branch

- Develops and revises regulations, guidelines, and criteria for State public water supply programs and State grants.
- Provides guidance to, and follows the progress of, Regions and States in the monitoring and administration of progress in Primacy and Non-Primacy States.
- Coordinates the Interstate Carrier water supply program on a Regional/State/local level.

### Ground Water Protection Branch

- Develops and revises regulations and guidelines for Underground Injection Control programs.
- Provides guidance to the Regions and States in the development and implementation of Underground Injection Control programs.

## TECHNICAL SUPPORT DIVISION

- Provides technical assistance to the Regions and States in the areas of operation and maintenance, monitoring and surveillance, treatment technology, and manpower development programs.
- Provides technical support for the use of available treatment techniques.
- Maintains a group of experienced personnel for technical support in emergency situations.
- Plans and prepares studies of the nature and extent of contaminants in public water supplies and ground water sources.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Office of Drinking Water | 202-426-8847 | WH-550 |
| Criteria and Standards Division | 202-472-5016 | WH-550 |
| Health Effects Branch | 202-472-6820 | WH-550 |
| Science and Technology Branch | 202-472-5030 | WH-550 |
| State Programs Division | 202-426-8290 | WH-550 |
| Drinking Water Branch | 202-472-4152 | WH-550 |
| Ground Water Protection Branch | 202-426-3934 | WH-550 |
| Technical Support Division | 513-684-4374 | 555 Ridge Road<br>Cincinnati, Ohio<br>45268 |

*FTS numbers are the same

# STATUTORY AUTHORITIES

## The Safe Drinking Water Act

**Public Law 95-110 42 U.S.C. § 300**

Under the authority of the U.S. Public Health Service, standards for potable water were first issued in 1912 in an effort to prevent the spread of communicable diseases. Over the years, these standards were modified and expanded many times. The standards set limits for chemical and biological impurities affecting human health and also recommended limits for impurities that affected appearance, taste, or odor. Although the standards applied only to water systems on interstate carriers such as trains, planes, and buses, they were widely used as guidelines by most States and large cities. With the establishment of the Environmental Protection Agency in 1970, the authority to set and enforce interstate drinking water standards was transferred to EPA from the Public Health Service.

The Safe Drinking Water Act (SDWA), passed by Congress in 1974 and amended in 1977, was designed to protect the public drinking water supplies by assuring that minimum national standards for the protection of human health were met. The Act, which was designated as Section XIV of the Public Health Service Act, gives EPA the authority to set minimum drinking water standards for all public water systems in the Nation serving at least 25 people or having at least 15 connections. Implementation of the regulations rests primarily with the States. A State must apply for primary enforcement status (primacy) which requires that States have regulations at least as stringent as

Federal standards. To date, 45 States have received primary enforcement status. EPA has enforcement responsibility only within those States not granted primacy.

The following States have assumed primacy on the indicated dates:

| | | |
|---|---|---|
| 1. | Oklahoma | 04-30-77 |
| 2. | Connecticut | 05-07-77 |
| 3. | Louisiana | 05-16-77 |
| 4. | Mississippi | 06-20-77 |
| 5. | Nebraska | 06-23-77 |
| 6. | Alabama | 07-10-77 |
| 7. | Arkansas | 07-10-77 |
| 8. | Georgia | 08-07-77 |
| 9. | New York | 09-10-77 |
| 10. | Virginia | 09-10-77 |
| 11. | Iowa | 09-13-77 |
| 12. | Minnesota | 09-26-77 |
| 13. | Tennessee | 09-30-77 |
| 14. | South Carolina | 09-30-77 |
| 15. | Maine | 10-07-77 |
| 16. | Hawaii | 10-20-77 |
| 17. | Kentucky | 10-20-77 |
| 18. | Massachusetts | 12-01-77 |
| 19. | Texas | 01-30-78 |
| 20. | Michigan | 02-01-78 |
| 21. | Maryland | 02-13-78 |
| 22. | North Dakota | 02-18-78 |
| 23. | Florida | 02-18-78 |
| 24. | Wisconsin | 03-02-78 |
| 25. | Nevada | 03-30-78 |
| 26. | Kansas | 03-30-78 |
| 27. | Montana | 03-30-78 |
| 28. | Idaho | 03-30-78 |
| 29. | Washington | 03-30-78 |
| 30. | New Mexico | 04-02-78 |
| 31. | Delaware | 04-02-78 |
| 32. | West Virginia | 04-02-78 |
| 33. | Colorado | 05-07-78 |
| 34. | California | 06-02-78 |
| 35. | New Hampshire | 08-18-78 |
| 36. | Trust Terr. | 09-09-78 |
| 37. | Guam | 09-09-78 |
| 38. | Alaska | 09-22-78 |
| 39. | Arizona | 09-24-78 |
| 40. | Rhode Island | 11-22-78 |
| 41. | Ohio | 03-15-79 |
| 42. | Missouri | 09-23-79 |
| 43. | Virgin Islands | 09-23-79 |
| 44. | Illinois | 09-29-79 |
| 45. | New Jersey | 12-30-79 |

The following States are expected to get primacy during Fiscal Year 1980.

1. Utah
2. Vermont
3. Puerto Rico
4. North Carolina
5. Northern Mariana Islands
6. American Samoa

The following States are expected to get primacy after Fiscal Year 1980.

1. Indiana
2. Pennsylvania
3. Oregon
4. South Dakota
5. Wyoming

## Key Sections of Act--Toxics Focus

The Act is divided into four basic parts, which are further divided into subsections.

### Part A--Definitions

Part A defines some basic terms relevant to the Act. Several of the more important terms include:

**Primary Drinking Water Regulation.** A regulation which applies to public water systems, specifying contaminants which, in the judgment of the Administrator, may have any adverse effect on human health, and specifying for each contaminant either a maximum contaminant level (MCL) or if an MCL is not economically or technologically feasible, then a treatment technique which sufficiently reduces the contaminant level.

**Secondary Drinking Water Regulation.** Applies to public water systems, and specifies the recommended levels for any contaminant which may affect the odor or appearance of water, thereby causing the public to discontinue using it.

**Public Water System.** A system which provides piped water for human consumption, and has at least 15 service connections or serves at least 25 people.

**Contaminant.** Any physical, chemical, biological, or radiological substance or matter in water.

**Maximum Contaminant Level.** The maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

### Part B--Public Water Systems

| | |
|---|---|
| sec. 1412(a)(1) | Requires the Administrator to set primary drinking water regulations. |
| sec. 1412(c) | Requires the Administrator to promulgate secondary drinking water regulations. |
| sec. 1413 | Gives primary enforcement responsibility to the States allowing for Federal enforcement only in those cases where a State is unwilling or unable to enforce. |
| sec. 1415 | Lists the conditions under which a variance may be granted. |
| sec. 1416 | Provides for exemptions to the Act. |

## Part C--Protection of Underground Sources of Drinking Water

| | |
|---|---|
| sec. 1421 | Requires the Administrator to publish regulations to control underground injection of fluids which may endanger drinking water sources for public water systems. |
| sec. 1422 | Requires the Administrator to list in the Federal Register each State for which a control program is necessary and directs each listed State to adopt and implement the regulations developed under Section 1421. |

## Part D--Emergency Powers

| | |
|---|---|
| sec. 1431 | Directs the Administrator,in the absence of action by State authorities, to issue orders or commence civil actions to protect public health in the event a contaminant entering a public water system may pose an imminent or substantial hazard. |

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

For a discussion of the regulatory process within the Environmental Protection Agency, see page 199 of this publication.

## EXISTING REGULATIONS

### Safe Drinking Water Act

| | |
|---|---|
| Interim Primary Drinking Water Regulations | 40 CFR 141 |
| Secondary Recommended Maximum Contaminant Levels | 40 CFR 143 |

# TOXICS-RELATED ACTIVITIES*

## The Underground Injection Control Program

Part C of the Safe Drinking Water Act (SDWA) instructs the EPA to establish a national program to prevent underground injections of fluids which endanger drinking water sources. Congress intended the Underground Injection Control Program (UIC) to protect not only the ground water which already serves as a source of drinking water, but also ground water that could potentially serve as a source of drinking water in the future.

In keeping with these requirements EPA published on April 20, 1979, (44 FR 23738) its proposed regulations covering the State underground injection control programs. The final regulations are expected in 1980.

## Additives in Drinking Water

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

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*Note: Included here are those activities identified as toxics-related from the information provided by each agency or office at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions, as well as new additions, to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

# OFFICE OF SOLID WASTE

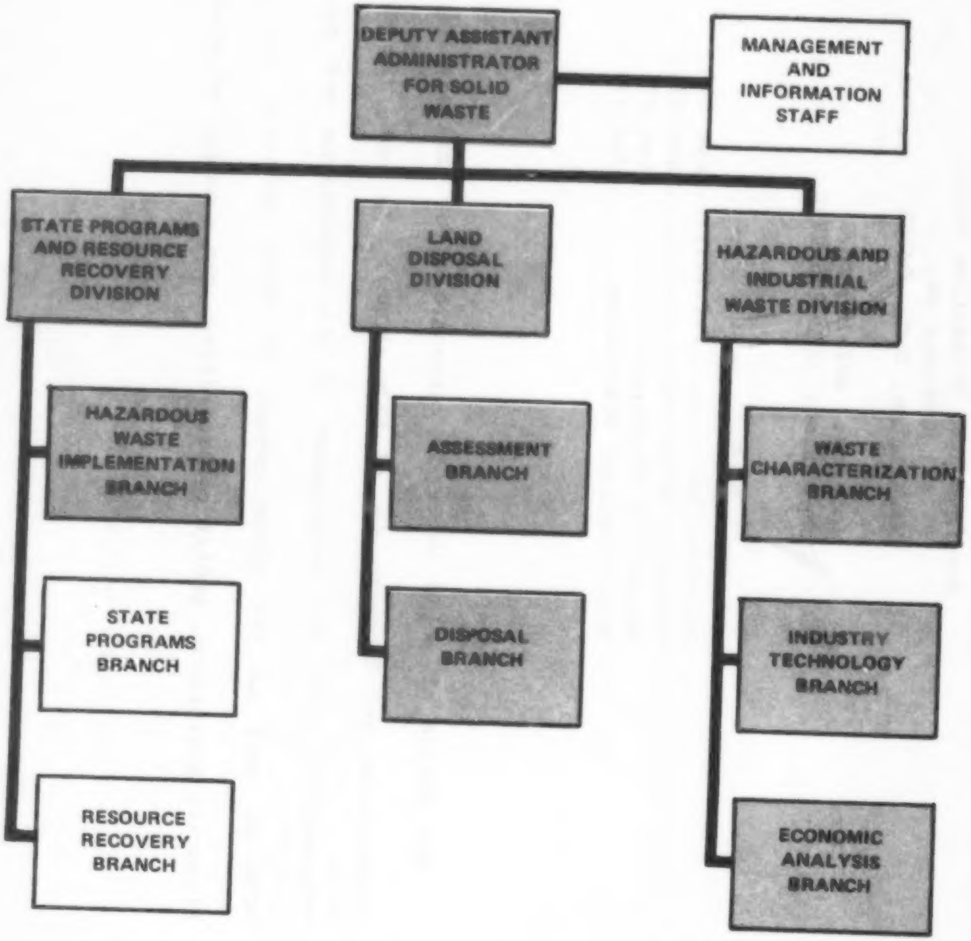
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

Organization....................page 271
Statutory Authority.............page 274
Regulatory Development..........page 276
Toxics-Related Activities.......page 277

The Office of Solid Waste is responsible for implementing the Resource Conservation and Recovery Act of 1976 (RCRA). As such, the Office has lead responsibility for the development of all regulations and guidelines under RCRA as well as the establishment of basic policies for technical and financial assistance, public participation, and a number of other programs.

# ENVIRONMENTAL PROTECTION AGENCY
# OFFICE OF WATER AND WASTE MANAGEMENT
## OFFICE OF SOLID WASTE
### ORGANIZATIONAL CHART*


DEPUTY ASSISTANT ADMINISTRATOR FOR SOLID WASTE
MANAGEMENT AND INFORMATION STAFF
STATE PROGRAMS AND RESOURCE RECOVERY DIVISION
LAND DISPOSAL DIVISION
HAZARDOUS AND INDUSTRIAL WASTE DIVISION
HAZARDOUS WASTE IMPLEMENTATION BRANCH
STATE PROGRAMS BRANCH
RESOURCE RECOVERY BRANCH
ASSESSMENT BRANCH
DISPOSAL BRANCH
WASTE CHARACTERIZATION BRANCH
INDUSTRY TECHNOLOGY BRANCH
ECONOMIC ANALYSIS BRANCH

*NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved in toxic substances activities.

# ORGANIZATION *

STATE PROGRAMS AND RESOURCE RECOVERY DIVISION

- Responsible for the nationwide implementation of a program to control hazardous wastes, control the land disposal of all solid wastes, and conserve resources through the recovery of solid and hazardous wastes.

Hazardous Waste Implementation Branch

- Provides guidance and support for the implementation of Subtitle C of RCRA.
- Develops standards and guidance for hazardous waste generators and transporters.
- Responsible for the hazardous waste permit and notification programs.

LAND DISPOSAL DIVISION

- Responsible for a national program to control and regulate the land disposal of all solid and hazardous waste.

Assessment Branch

- Establishes ground water quality criteria and sets up policies for protecting ground water supplies against the adverse effects of land disposal.

Disposal Branch

- Develops criteria, guidelines, and regulations for controlling the land disposal of solid and hazardous wastes, including sewage sludge.
- Assesses the technologies available for land disposal and application of wastes.
- Develops, in cooperation with the Office of Research and Development (EPA) and the Technology Branch of the OSW, technical performance standards for land disposal alternatives.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

## HAZARDOUS AND INDUSTRIAL WASTE DIVISION

- Develops regulations for the characterization and control of hazardous waste.
- Coordinates a national program of technology and environmental analysis and economic assessment for hazardous and solid wastes.
- Maintains liaison with the industrial community and the Office of Pesticides and Toxic Substances (EPA).

### Waste Characterization Branch

- Manages technical studies, provides technical support in regulatory matters, and makes determinations on hazardous waste characteristics and lists.
- Responsible for developing and validating hazardous waste sampling methods, designing test protocols, and evaluating chemical and biological tests for their application to the listing and characterization process.
- Develops information on waste streams used in defining criteria for hazardous waste.

### Industry Technology Branch

- Promulgates regulations and guidelines for the storage, treatment, incineration, and recovery of hazardous wastes. In developing the regulations, the Branch studies the performance, availability, and costs of various technological methods.
- Assesses industrial solid waste management practices.
- Develops Federal guidelines for procurement of products containing recycled materials.

### Economic and Policy Analysis Branch

- Prepares economic assessments and environmental impact statements.
- Economic analyses focus on the economic impact of hazardous and solid waste regulatory programs and include both industrial and public facilities.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone* | Mail Stop |
|---|---|---|
| Office of Solid Waste | 202-755-9170 | WH-562 |
| Land Disposal Division | 202-755-9130 | WH-564 |
| Assessment Branch | 202-755-9116 | WH-564 |
| Disposal Branch | 202-755-9120 | WH-564 |
| State Programs and Resource Recovery Division | 202-755-9170 | WH-563 |
| Hazardous and Industrial Waste Division | 202-755-9185 | WH-565 |
| Waste Characterization Branch | 202-755-9187 | WH-565 |
| Industry Technology Branch | 202-755-9200 | WH-565 |
| Economic Analysis Branch | 202-755-9190 | WH-565 |

*FTS numbers are the same

# STATUTORY AUTHORITIES

## The Resource Conservation and Recovery Act of 1976

Public Law 94-580 48 U.S.C. § 6901

Passage of the Resource Conservation and Recovery Act of 1976 (RCRA) updated and amended the Solid Waste Disposal Act of 1965. The principal goal of RCRA is to protect public health and the environment by controlling the disposal of solid waste and regulating the management and handling of hazardous waste materials. In addition, the Act is designed to promote the conservation of natural resources through the recovery of usable energy and materials. RCRA authorizes the Environmental Protection Agency to regulate hazardous wastes from their generation to disposal; to foster establishment of regulatory programs in the States for controlling the disposal of solid wastes on land and prohibiting the use of open dumps; and to assist in developing national conservation and recovery policies.

### Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 1008 | Directs the Administrator to develop and publish criteria for solid waste management. |
| sec. 3001 | Authorizes the development of criteria for identifying hazardous wastes. |
| sec. 3002 | Authorizes the development of standards regulating the generators of hazardous wastes. |
| sec. 3003 | Authorizes the development of standards governing the transportation of hazardous wastes. |
| sec. 3004 | Authorizes the development of standards for the treatment, storage, and disposal of hazardous wastes. |

| | |
|---|---|
| sec. 3005 | Authorizes the issuance of permits for facilities for treatment, storage, and disposal of hazardous waste. |
| sec. 3006(a) | Directs the Administrator to promulgate guidelines to assist the States in developing their own hazardous waste programs. |
| sec. 3006(b) | Authorizes the States to administer their approved programs. |
| sec. 3007 | Grants the Administrator authority to inspect hazardous waste facilities. |
| sec. 4004 | Authorizes development of criteria for classification of sanitary landfills. |
| sec. 4005(b) | Requires an inventory of all "open dump" disposal sites in the United States. |
| sec. 4005(c) | Requires the closing or upgrading of those sites which do not meet the sanitary landfill criteria. |
| sec. 7003 | Directs the Administrator to bring suit or take other legal action when solid or hazardous wastes present a danger to public health or the environment. |

## Regulatory Options Available Under Statute

- Authorizes the Environmental Protection Agency to develop, and the States to enforce, EPA standards governing the generation, transportation, treatment, storage, and disposal of hazardous wastes.
- Authorizes States to establish programs for the closing or upgrading of open dumps and directs States to include these programs within their Solid Waste Management plan.

# REGULATORY DEVELOPMENT PROCESS

## REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 199 of this publication.

## EXISTING REGULATIONS

| | |
|---|---|
| Resource Conservation and Recovery Act | 40 CFR 240-255 |

# TOXICS-RELATED ACTIVITIES*

## Hazardous Waste Management Program

Under Subtitle C (Hazardous Waste Management) the main effort to date has focused on the development of regulations for hazardous wastes from the point of generation through their ultimate disposal. The following regulations are scheduled for issuance in 1980.

Hazardous Waste Criteria--Identification and Listing--RCRA 3001. These regulations define wastes that will be controlled under the nationwide Hazardous Waste Management Program. Criteria are provided to identify characteristics of hazardous wastes, based on ignitability, corrosiveness, reactivity, and toxicity. Also included are testing procedures to determine whether a waste meets the described characteristics. The regulation also lists certain hazardous wastes and processes which are presumed to generate hazardous wastes. Means are also provided for demonstration of noninclusion in the Subtitle C system.

Standards for Generators of Hazardous Wastes--RCRA 3002. This regulation establishes national standards for generators of hazardous wastes, covering such items as recordkeeping, containerization and labeling, waste identification, and reporting. This regulation also contains provisions for a hazardous waste manifest system.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. If you are aware of any such omissions or new additions, please bring them to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

Standards for Transporters of Hazardous Wastes--RCRA 3003. These national standards require transporters of hazardous waste to ship only properly labeled containers and only to permitted facilities.

Standards for Hazardous Waste Treatment Storage and Disposal Facilities--RCRA 3004. Hazardous waste management facilities will be required to meet certain standards of administration, financial responsibility, and technical performance regarding operating procedures, location, and design. These standards contain provisions to protect surface water, ground water, and air quality.

Permit Regulations for Hazardous Waste Treatment, Storage, and Disposal Facilities--RCRA 3005 and Guidelines for State Hazardous Waste Programs--RCRA 3006. As part of EPA's Consolidated Permit Regulations, these regulations establish a permit program to assure uniform State (or EPA) control of hazardous waste management facilities and assist States in developing their own hazardous waste regulatory programs. The guidelines also specify minimum requirements States must meet in order to be authorized by EPA to implement these programs.

## Solid Waste Management--RCRA Subtitle D

Wastes not classified as hazardous or exempt from Subtitle C because of low generation rates (under Section 3001) will be disposed of in sites regulated under Subtitle D (State or Regional Solid Waste Plans) of RCRA. While not considered hazardous under the definition of the Act, many of the wastes disposed of in these facilities nonetheless have the potential for creating hazardous environmental conditions. To ensure the safe disposal of these wastes, the Act requires the closure or upgrading of all open dumps under Section 4005 and requires EPA to issue Criteria for the Identification of Sanitary Landfills under Section 4004. Section 4005 also requires that all disposal facilities be inventoried and a determination made as to whether they meet the Landfill Criteria. Those facilities not meeting the criteria are classified as open dumps and therefore must be closed or upgraded. The Landfill Criteria became effective September 13, 1979.

# *OFFICE OF AIR, NOISE, AND RADIATION*

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

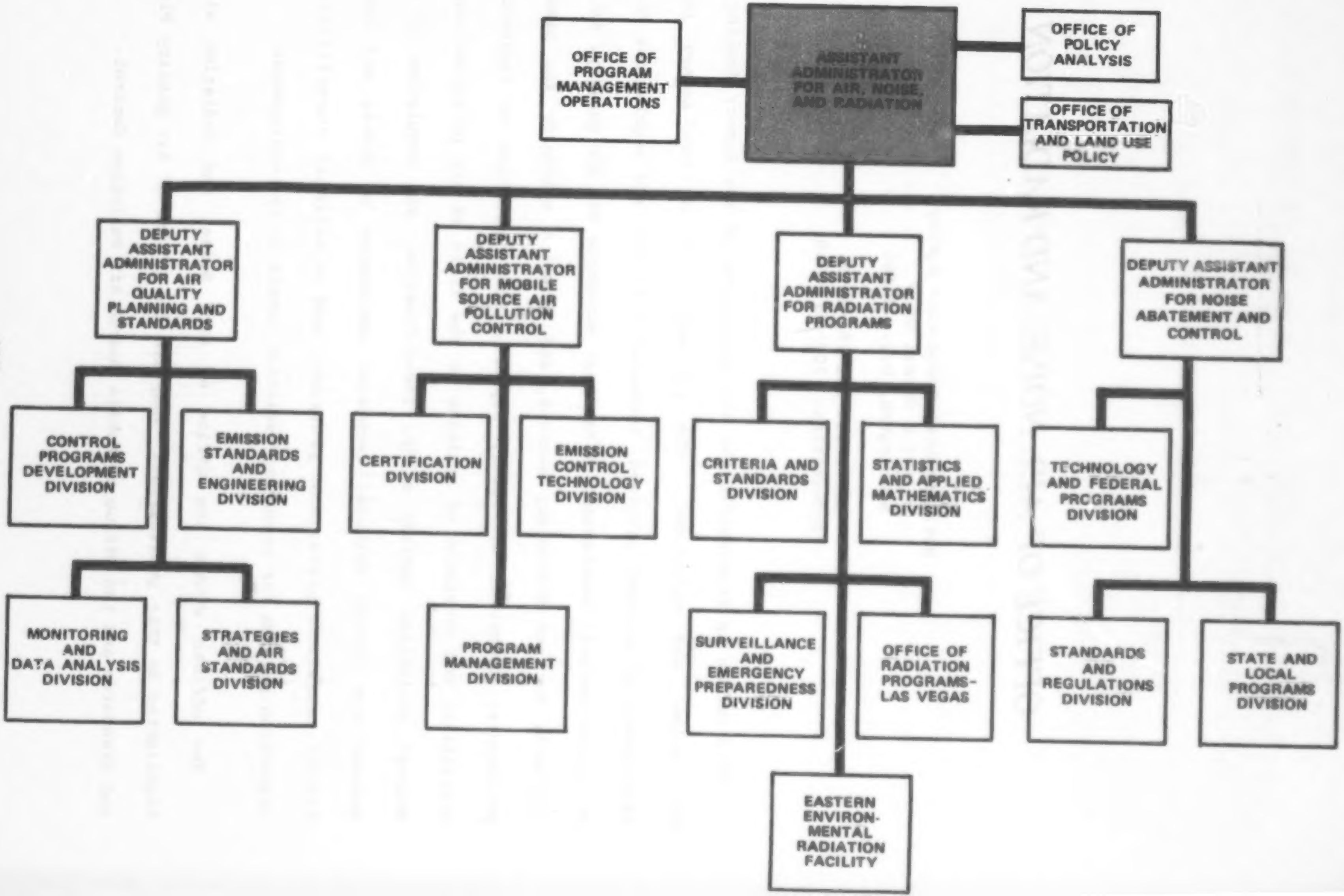
Locator: 202-755-2673
Information: 202-755-0720

This Office is responsible for the activities of the Agency dealing with air, noise, and radiation. The air activities of the Agency include development of national programs, technical policies, and regulations for air pollution control; development of national standards for air quality, emission standards for new stationary sources, and emission standards for hazardous pollutants; technical direction, support, and evaluation of regional air activities; and provision of training in the field of air pollution control. Related activities include study, identification, and regulation of noise sources and control methods; technical assistance to States and agencies having radiation protection programs; and a national surveillance and inspection program for measuring radiation levels in the environment.

Two offices within the Office of Air, Noise, and Radiation will be highlighted in this publication. They are the Office of Air Quality Planning and Standards and the Office of Mobile Source Air Pollution Control.

# ENVIRONMENTAL PROTECTION AGENCY

# OFFICE OF AIR, NOISE, AND RADIATION


OFFICE OF PROGRAM MANAGEMENT OPERATIONS
ASSISTANT ADMINISTRATOR FOR AIR, NOISE, AND RADIATION
OFFICE OF POLICY ANALYSIS
OFFICE OF TRANSPORTATION AND LAND USE POLICY
DEPUTY ASSISTANT ADMINISTRATOR FOR AIR QUALITY PLANNING AND STANDARDS
DEPUTY ASSISTANT ADMINISTRATOR FOR MOBILE SOURCE AIR POLLUTION CONTROL
DEPUTY ASSISTANT ADMINISTRATOR FOR RADIATION PROGRAMS
DEPUTY ASSISTANT ADMINISTRATOR FOR NOISE ABATEMENT AND CONTROL
CONTROL PROGRAMS DEVELOPMENT DIVISION
EMISSION STANDARDS AND ENGINEERING DIVISION
CERTIFICATION DIVISION
EMISSION CONTROL TECHNOLOGY DIVISION
CRITERIA AND STANDARDS DIVISION
STATISTICS AND APPLIED MATHEMATICS DIVISION
TECHNOLOGY AND FEDERAL PROGRAMS DIVISION
MONITORING AND DATA ANALYSIS DIVISION
STRATEGIES AND AIR STANDARDS DIVISION
PROGRAM MANAGEMENT DIVISION
SURVEILLANCE AND EMERGENCY PREPAREDNESS DIVISION
OFFICE OF RADIATION PROGRAMS-LAS VEGAS
STANDARDS AND REGULATIONS DIVISION
STATE AND LOCAL PROGRAMS DIVISION
EASTERN ENVIRON-MENTAL RADIATION FACILITY

# OFFICE OF AIR QUALITY PLANNING AND STANDARDS

U.S. EPA (MD-11)
Research Triangle Park, NC 27711

Locator: 919-541-5411
8-629-5411

Information: 919-541-5411
8-629-5411

# OFFICE OF MOBILE SOURCE AIR POLLUTION CONTROL

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

Organization.....................page 286
Statutory Authority..............page 289
Regulatory Development...........page 292
Toxics-Related Activities........page 293

The Office of Air Quality Planning and Standards is responsible for the air quality planning and standards functions of the Agency. As such, this Office develops national standards for air quality, emission standards for new stationary sources, and emission standards for hazardous pollutants. In

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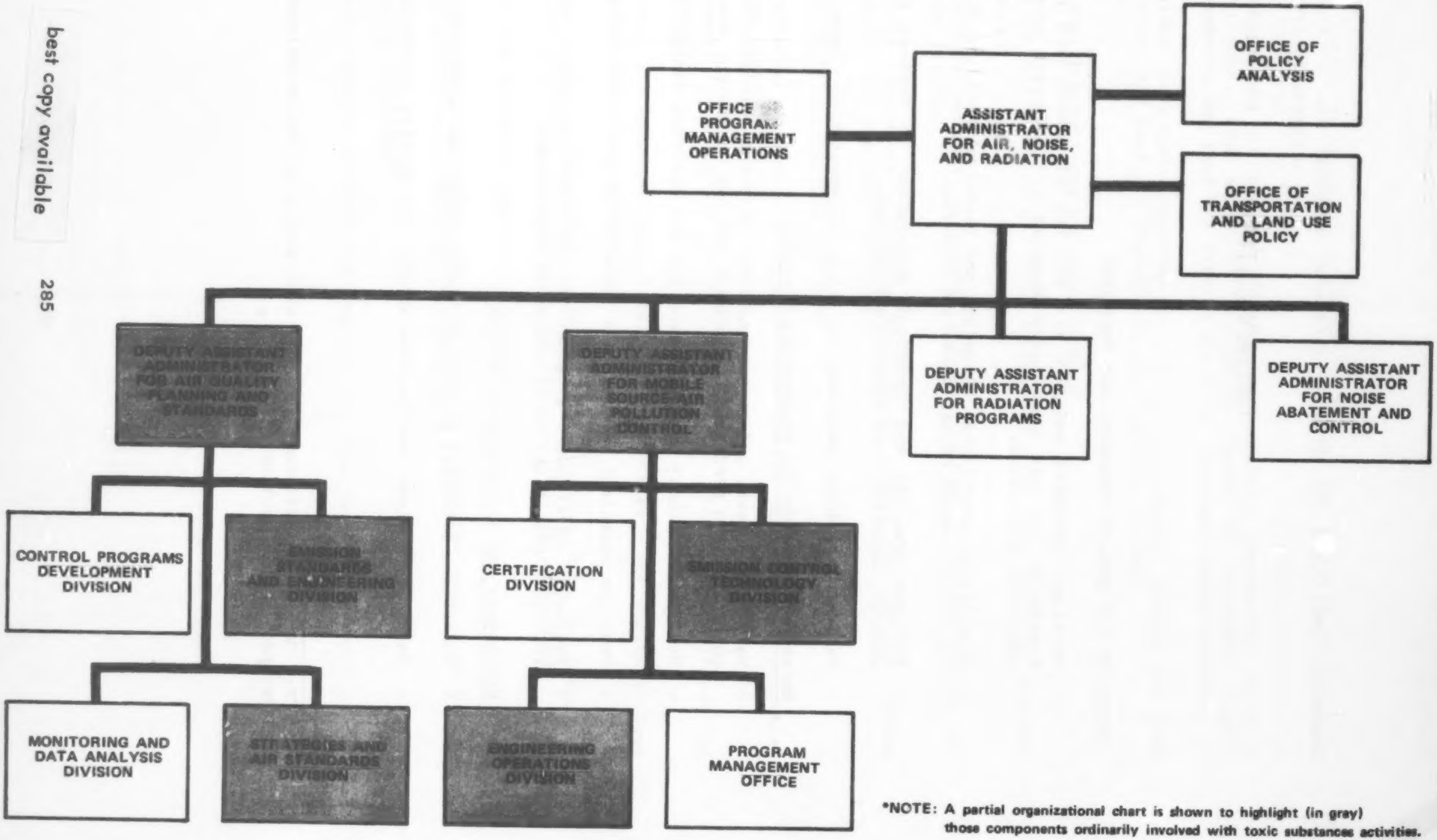
*NOTE: Since both of these Offices are responsible for implementing activities under The Clean Air Act, they are covered in the same section of this publication. This represents a slight change in format.

addition, the Office develops national programs, technical policies, regulations, guidelines, and criteria for air pollution control; assesses the national air pollution control program; and provides assistance to States and the Regional Offices.

The Office for Mobile Source Air Pollution Control has the responsibility for the mobile source air pollution control functions of the Agency. The Office is responsible for characterizing emissions from mobile sources and then developing programs for their control; developing and recommending emission standards and related test procedures for mobile sources; and carrying out a regulatory compliance program to ensure adherence of mobile sources to standards.

## ENVIRONMENTAL PROTECTION AGENCY*
## OFFICE OF AIR, NOISE, AND RADIATION
## OFFICE OF AIR QUALITY PLANNING AND STANDARDS
## OFFICE FOR MOBILE SOURCE AIR POLLUTION CONTROL


ASSISTANT ADMINISTRATOR FOR AIR, NOISE, AND RADIATION
OFFICE OF PROGRAM MANAGEMENT OPERATIONS
OFFICE OF POLICY ANALYSIS
OFFICE OF TRANSPORTATION AND LAND USE POLICY
DEPUTY ASSISTANT ADMINISTRATOR FOR AIR QUALITY PLANNING AND STANDARDS
DEPUTY ASSISTANT ADMINISTRATOR FOR MOBILE SOURCE AIR POLLUTION CONTROL
DEPUTY ASSISTANT ADMINISTRATOR FOR RADIATION PROGRAMS
DEPUTY ASSISTANT ADMINISTRATOR FOR NOISE ABATEMENT AND CONTROL
CONTROL PROGRAMS DEVELOPMENT DIVISION
EMISSION STANDARDS AND ENGINEERING DIVISION
CERTIFICATION DIVISION
EMISSION CONTROL TECHNOLOGY DIVISION
MONITORING AND DATA ANALYSIS DIVISION
STRATEGIES AND AIR STANDARDS DIVISION
ENGINEERING OPERATIONS DIVISION
PROGRAM MANAGEMENT OFFICE

*NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

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# ORGANIZATION*

## OFFICE OF AIR QUALITY PLANNING AND STANDARDS

- Develops national ambient air quality standards and performance standards for new stationary sources and emission standards for hazardous pollutants.
- Establishes guidelines, criteria, and technical policies for assessing the effectiveness of air pollution controls.
- Provides training and technical information to States, EPA Regional Offices, industry, and other organizations.
- Evaluates regional programs and State implementation plans.

### Emission Standards and Engineering Division

- Develops reviews, and revises national emission standards for hazardous pollutants and performance standards for new stationary sources.
- Studies stationary source categories and analyzes control methods and economic information.
- Provides technical expertise in emission control technologies.
- Evaluates development alternatives for their technical soundness and for their compatibility to emissions regulations.

### Strategies and Air Standards Division

- Identifies potential pollutants and analyzes new control strategies.
- Develops, reviews, and revises ambient air quality standards.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Identifies and analyzes potential effects of identified pollutant control strategies.

- Develops new or revises former air quality standards, control techniques, and emission standards, based on economic impact assessments and land use studies which the Division itself conducts.

- Provides technical expertise in control strategies, energy and fuel policies, and land use planning to EPA Regional Offices.

## OFFICE FOR MOBILE SOURCE AIR POLLUTION CONTROL

- Characterizes emissions from mobile sources and develops control programs.

- Recommends emission standards and any related test procedures for mobile sources.

- Conducts regulatory compliance programs to ensure that mobile sources adhere to the standards developed.

### Emission Control Technology Division

- Characterizes current emissions from mobile sources for potential future control.

- Evaluates the technical possibility and cost effectiveness of control strategies.

- Assesses and develops control technologies for existent mobile sources to establish future standards.

- Develops and disseminates technical and economic data on near-term control technology for national and regional control strategies.

- Tests and evaluates control techniques.

- Develops and coordinates emissions testing procedures with other public and industry emissions testing laboratories.

### Engineering Operations

- Conducts vehicle testing and supports the test facility operations.

## DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

| Division/Office | Phone | Mail Stop |
|---|---|---|
| Office of Air Quality Planning and Standards | 919-541-5411<br>8-629-5411 | MD-11<br>Research Triangle Park, NC 27711 |
| Emission Standards and Engineering Division | 919-541-5271<br>8-629-5271 | MD-13<br>Research Triangle Park, NC 27711 |
| Strategies and Air Standards Division | 919-541-5204<br>8-629-5204 | MD-12<br>Research Triangle Park, NC 27711 |
| Office for Mobile Source Air Pollution Control | 202-426-2464<br>8-426-2464 | ANR-455<br>401 M Street SW.<br>Washington DC 20460 |
| Emission Control Technology Division | 313-668-8404<br>8-374-8404 | 2565 Plymouth Road<br>Ann Arbor, MI 48105 |
| Engineering Operations Division | 313-668-8243<br>8-374-8243 | 2565 Plymouth Road<br>Ann Arbor, MI 48105 |

# STATUTORY AUTHORITY

## Clean Air Act

### Public Law 95-11 42 U.S.C. § 7401 et seq.

The Federal mandates for reducing air pollution and improving air quality are embodied in legislation originally passed in 1955 and strengthened in 1963, 1965, and 1967. Strong national control legislation came with the 1970 and 1977 amendments to the Clean Air Act.

### 1970 Amendments

Before 1970, the Act provided for national control of motor vehicle emissions studies as well as nationwide planning of possible control methods, and empowered States to set pollution control goals.

The 1970 amendments required the Federal Government to set standards for ambient air quality. These standards were to define the principal types of pollution and the levels of each that should not be exceeded for the protection of public health and welfare. EPA formally adopted the first ambient air quality standards in 1971.

### 1977 Amendments

In the late 1960's study and planning efforts had been based on individual air quality regions, on the presumption that air pollution problems (and their solutions) would vary from place to place throughout the country. An air quality region was defined as an area with definite pollution problems, common pollution sources, and characteristic weather. Though the geographical boundaries were seldom exact, the air quality regions were useful units for management and control; each region had individual problems and individual characteristics.

The regional concept is still in use in the planning and control measures being carried out by EPA and the various States, and the 1977 amendments require the States to rate each region for its attainment of each air quality standard.

In addition, Congress strengthened efforts to maintain air quality in regions where the air is already clean. There cannot be any "significant deterioration" of air quality in such regions. The law specifies how sulfur oxides and particulates will first be regulated in "clean-air regions," and anticipates later regulation of other pollutants.

Three kinds of "clean-air regions" are defined. Class 1 must include all national parks and wilderness areas any may include further areas named by the States to remain unsullied. Class 11 areas can have some industrial development, up to specified levels. Class III areas can have about twice as much pollution from additional new sources, sometimes up to the minimum Federal Standards.

Any potential pollution source--factory, power plant, or other--that is proposed must first obtain a permit and meet a number of conditions, which include using the best available control methods for the new source.

Industrial development is also permitted in polluted regions as long as offsetting reductions are made in that region's existing sources. A new tire factory, for instance, although it meets the new source performance standards for the rubber industry, would still add more pollution to the region. Under the new amendments, the factory can be built if existing sources reduce their emissions more than enough to compensate for the new plant.

## Key Sections of Act--Toxics Focus

| | |
|---|---|
| sec. 108 | Authorizes EPA to establish air quality criteria and control techniques for air pollutants from both stationary and mobile sources. |
| sec. 109 | Gives EPA authority to prescribe national ambient air quality standards. |
| sec. 110 | Establishes State implementation plans for attainment of air quality standards. |
| sec. 111 | Authorizes the establishment of standards for performance of new stationary sources of air pollutants; incorporates State plans for implementing new source performance standards programs. |
| sec. 112 | Defines hazardous air pollutants and authorizes the establishment of emission standards for such pollutants; authorizes EPA to impose alternative controls when emission standards are not feasible. |
| sec. 202 | Authorizes motor vehicle emission standards and in some cases, sets the standards. |
| sec. 211 | Requires registration of fuel and fuel additives. |
| sec. 303 | Gives EPA emergency powers to act to stop air pollution emissions if necessary to protect against imminent dangers to health. |

## Regulatory Options Available Under Statute

- Designation of criteria pollutants and establishment of ambient air quality standards
- Imposition of new source performance standards on a category of emitter--can entail numerical limit or engineering control
- Listing as a hazardous air pollutant on health grounds and imposition of controls on all emitters--as a numerical standard or engineering control
- Imposition of land use controls in nonattainment areas
- Use of emergency powers in case of imminent hazard--litigation for RO/TRO

# REGULATORY DEVELOPMENT

## REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 199 of this publication.

## EXISTING REGULATIONS

| | |
|---|---|
| CLEAN AIR ACT | 40 CFR 50-87 |

# TOXICS-RELATED ACTIVITIES*

## New Source Performance Standards

New Source Performance Standards are specific limits applicable to individual industries. They set the maximum amounts of each kind of pollutant such as sulfur dioxide or particulates that can be emitted from new plant smokestacks for each unit of the plant's production. Standards of performance are proposed following a detailed investigation of air pollution control methods available to the industry and the impact of their cost to the industry. The investigations are conducted to ensure that standards: (1) realistically reflect best demonstrated control practices; (2) adequately consider the cost, nonair quality health and environmental impacts, and energy requirements of such control; (3) are applicable to existing sources that are modified or reconstructed as well as new installations; and (4) meet these conditions for all variations of operating conditions being considered anywhere in the country. Nationwide standards for new sources are intended to discourage industrial plants from moving to States with less stringent regulations. Under the Federal standards, the industry would have to build a new plant in compliance with the new source performance standards.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

## National Emission Standards for Hazardous Pollutants

Under the authority of Section 112(b)(1) of the Clean Air Act, EPA may propose national emission standards for specific air pollutants that are particularly hazardous to health. Proposed standards are based on the best available control technology (BACT) for both new and existing sources of the pollutant and limit the amounts which owners and operators of plants emitting the pollutant may discharge into the atmosphere. To arrive at the proposed limits, EPA considers beneficial and adverse economic, environmental, and energy impacts associated with both the proposed standard, and its alternatives.

## Motor Vehicle Emission Laboratory

The Motor Vehicle Emission Laboratory (MVEL) is staffed by three Divisions and numerous support groups. They are responsible for characterizing motor vehicle emissions, assessing new technology, developing test procedures, developing regulations and helping establish emission inspection and maintenance programs.

# Programs

# *NATIONAL TOXICOLOGY PROGRAM*

Public Health Service
Department of Health and Human Services
P.O. Box 12233
Research Triangle Park, N.C. 27709

Information: 919-541-3780
8-629-3780
(Ms. Leslie Gardner)

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NTP Program and Project Leaders......page 301
Chemical Selection Principles........page 304

## Overview and General Information

The National Toxicology Program (established in November 1978) develops scientific information about potentially toxic and hazardous chemicals which can be used for protecting the health of the American people and for the primary prevention of chemically-induced disease. The National Toxicology Program centralizes and strengthens the Department of Health and Human Services' (DHHS) activities in toxicology testing and test development/validation efforts and provides toxicological information needed by research and regulatory agencies. Three specific goals have been identified:

- to expand the toxicological profiles of the chemicals nominated, selected, and being tested;
- to increase the number and rate of chemicals under test;
- to develop, coordinate, and validate a series of tests/protocols more appropriate for regulatory needs.

The National Toxicology Program's Charter Agencies. Presently, the four DHHS agencies whose relevant toxicology programs comprise the NTP are the National Cancer Institute, National Institutes of Health; National Institute of Environmental Health Sciences, National Institutes of Health; National Center for Toxicological Research, Food and Drug Administration; National Institute for Occupational Safety and Health, Center for Disease Control.

The NTP Executive Committee provides linkage between DHHS research and regulatory agencies to ensure that the NTP toxicology research, testing, and test development are responsive to regulatory needs and to the wants of the public. This unique aspect of the NTP brings together the research and regulatory agencies doing fundamental biomedical research. The current members representing those governmental agencies that comprise the NTP Executive Committee are:

- Dr. Eula Bingham (Chairperson), Assistant Secretary of Labor, Occupational Safety and Health Administration
- Honorable Douglas M. Costle, Administrator, Environmental Protection Agency
- Dr. Donald Fredrickson, Director, National Institutes of Health
- Dr. David P. Rall, Director, National Institute of Environmental Health Sciences
- Dr. Julius B. Richmond (non-voting), Assistant Secretary for Health, Department of Health and Human Services
- Dr. Vincent deVita, Jr., Acting Director, National Cancer Institute.

The NTP Board of Scientific Counselors provides scientific oversight of the NTP; advises the NTP Director and the NTP Executive Committee on scientific content, philosophy, and policy; and evaluates the merit and overall quality of the science conducted in the NTP components. These eight scientists have been appointed by the Secretary of the Department of Health and Human Services:

- Joseph C. Dunbar, Ph. D., Associate Professor of Physiology, Wayne State University School of Medicine (1982)
- Curtis Harper, Ph. D., Associate Professor of Pharmacology, University of North Carolina School of Medicine (1981)
- Margaret Hitchcock, Ph. D., Assistant Professor of Pharmacology, Yale University Medical School (1983)
- Marjorie G. Horning, Ph. D., Professor of Biochemistry, Baylor College of Medicine (1983)
- Mortimer L. Mendelsohn, M.D., Ph. D., Director, Biomedical Sciences Division, Lawrence Livermore Laboratory, University of California (1982)
- Norton Nelson, Ph. D., (Chairperson), Professor of Environmental Medicine, New York University School of Medicine (1983)
- Thomas H. Shepard, M.D., Professor of Pediatrics and Head of Central Laboratory for Human Embryology, University of Washington School of Medicine (1981)
- Alice S. Whittemore, Ph. D., Adjunct Professor of Family, Community, and Preventive Medicine, Stanford University (1983).

NTP Annual Plans. The development and approval of the NTP Annual Plan remains central to the effective planning, coordination, and operation of the National Toxicology Program. As NTP Director, Dr. David P. Rall (also the Director of the National Institute of Environmental Health Sciences) reports to the Assistant Secretary for Health.

The 1980 NTP Annual Plan contains information on the NTP research, testing, and validation efforts for the coming fiscal year as well as for the previous fiscal year. This 117-page report divides into 10 sections: Introduction and Executive Summary, Background, Participating Agencies, Oversight and Review, Planning Assumptions and Program Balance, Organization, Toxicology Research and Testing Overview, Coordinative Management Activities, Information Generation and Dissemination, Annual Report on Carcinogens.

A companion to the NTP Annual Plan is the 334-page NTP Review of Current DHHS Research Related to Toxicology. This compilation emphasizes three major areas: DHHS Agencies' Role in the Support of Toxicology Research, Testing, and Method Development; Chemical Compounds Currently Being Tested by DHHS Agencies for Toxicological Properties; Toxicology Methods Currently Being Developed by DHHS Agencies.

To bridge the yearly gap between Annual Plans, NTP has started an NTP Technical Bulletin to keep those persons or groups interested in the NTP informed about the NTP's most current and proposed activities. The NTP Technical Bulletins augment the Annual Plans by more timely and frequent announcements of the NTP research activities and specific actions.

For those wanting more information about the National Toxicology Program as well as to receive the NTP Annual Plan for Fiscal Year 1980, the NTP Review of Current DHHS Research Related to Toxicology, or the NTP Technical Bulletin, please indicate which publications you wish to receive and return this information to:

Ms. Leslie Gardner
National Toxicology Program
P.O. Box 12233
Research Triangle Park, NC 27709

## NTP Programs and Project Leaders

The program segments of the NTP are grouped into two categories--toxicologic research and testing, and coordinative management activities. Individual NTP scientists have been appointed as Leaders of major program segments. Each scientist serves as the center for a particular program activity and is responsible for developing (in collaboration with other NTP colleagues) the subprogram activities, the implementation plan, as well as the coordination and supervision of the program work. Programs and Project Leaders are listed in the following table.

## MAJOR NATIONAL TOXICOLOGY PROGRAM AREAS AND LEADERS

| Area | Leader | Contributing Agency* | Telephone | FTS |
|---|---|---|---|---|
| Director | Dr. D. P. Rall | NTP | 919-541-3201 | 629-3201 |
| Deputy Director | Dr. J. A. Moore | NTP | 919-541-3267 | 629-3267 |
| Toxicologic Research and Testing | | | | |
| Carcinogenesis | Dr. R. Griesemer | NCI | 202-496-5591 | same |
| Short-Term Test Development | Vacant | | | |
| Tumor Pathology | Dr. J. Ward | NCI | 202-496-6868 | same |
| Chemical Disposition | Dr. H. Matthews | NIEHS | 919-541-3369 | 629-3369 |
| General Toxicology | Dr. J. Moore | NTP | 919-541-3267 | 629-3267 |
| Toxicopathology | Dr. E. McConnell | NIEHS | 919-541-3231 | 629-3231 |
| Genetic Toxicology | Dr. E. Zeiger | NIEHS | 919-541-4482 | 629-4482 |
| Immunologic Toxicology | Dr. J. Dean | NIEHS | 919-541-4659 | 629-4659 |
| Neurobehavioral Toxicology | Dr. C. Mitchell | NIEHS | 919-541-3220 | 629-3220 |
| Pulmonary Toxicology | Dr. T. Lewis | NIOSH | 513-684-8392 | same |
| Reproductive and Developmental Toxicology | Dr. J. Holson | NCTR | 501-542-4303 | same |

## MAJOR NATIONAL TOXICOLOGY PROGRAM AREAS AND LEADERS (cont.)

| Area | Leader | Contributing Agency* | Telephone | FTS |
|---|---|---|---|---|
| Coordinative Management Activities | | | | |
| Bioassay Coordination | Dr. J. F. Douglas | NCI | 202-496-5591 | same |
| Chemical Nomination | Dr. L. Fishbein | NCTR | 501-542-4390 | same |
| Chemical Repository | Dr. C. Jameson | NCI | 202-496-1152 | same |
| | Dr. D. Walters | NIEHS | 919-541-3355 | 629-3355 |
| Data Management and Analysis | Dr. M. Hoel** | NIEHS | 919-541-3205 | 629-3205 |
| Carcinogenesis | Dr. K. Chu | NCI | 202-496-1152 | same |
| Mutagenesis | Dr. B. Margolin | NIEHS | 919-541-3460 | 629-3460 |
| Toxicology | Dr. J. Moseman | NIEHS | 919-541-3437 | 629-3437 |
| TDMS (Development) | Mr. A. Konvicka | NCTR | 501-542-4534 | 629-4534 |
| Information Dissemination | Dr. J. E. Huff | NTP | 919-541-3780 | 629-3780 |
| Laboratory Animal Quality Control | Vacant | | | |
| Laboratory Health and Safety | Dr. H. Maher | NCI | 202-496-9526 | same |
| Technical Information | Dr. H. Kissman | NLM | 202-496-3147 | same |

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*Addresses: National Cancer Institute, Bethesda, MD 20205; National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709; National Library of Medicine, Bethesda, MD 20014; National Toxicology Program, Research Triangle Park, NC 27709; National Institute for Occupational Safety and Health, Cincinnati, OH 45226; National Center for Toxicological Research, Jefferson, AR 72079.

**Dr. J. Maseman, Acting Program Leader

## NTP Chemical Selection Principles

The NTP Executive Committee operates under the principle that industry will test chemicals for health and environmental effects as intended and mandated by the Congress under legislative authorities. Therefore, the NTP, acting under its chemical selection principles, will test:

1. Chemicals found in the environment that are not closely associated with commercial activities;

2. Desirable substitutes for existing chemicals, particularly therapeutic agents, that might not be developed or tested without Federal involvement;

3. Chemicals that should be tested to improve scientific understanding of structure-activity relationships and thereby assist in defining groups of commercial chemicals that should be tested by industry;

4. Certain chemicals tested by industry, or by others, the additional testing of which by the Federal Government is justified to verify the results;

5. Previously tested chemicals for which other testing is desirable to cross-compare testing methods;

6. "Old chemicals" with the potential for significant human exposure which are of social importance but which generate too little revenue to support an adequate testing program (some of these may be "grandfathered" under FDA laws);

7. Two or more chemicals together, when combined human exposure occurs (such testing probably cannot be required of industry if the products of different companies are involved); and

8. In special situations, as determined by the Executive Committee, marketed chemicals which have potential for large-scale and/or intense human exposure, even if it may be possible to require industry to perform the testing.

Chemical Nomination. NTP urges all those interested in proposing chemical(s) for testing to do so, and to recommend the type test(s) to be considered and to supplement each nomination with the following necessary information, if known:

I. Chemical Identification

   a. Chemical Abstracts Service (CAS) preferred name
   b. Common or generic name and synonyms

- c. CAS Registry Number
- d. Chemical class and related compounds
- e. Physical and chemical properties

    - i. Physical description
    - ii. Structural and molecular formula and molecular weight
    - iii. Melting and boiling points
    - iv. Solubility
    - v. Stability and reactivity
    - vi. Other relevant information

- f. Commercial product(s) composition
- g. References

II. Production, Use, Occurrence, and Analysis

- a. Production

    - i. Source and synthesis, year and pathway of first production
    - ii. Current production and pathway

- b. Uses
- c. Occurrence in the Environment

    - i. Naturally occurring
    - ii. Air, water, and soil
    - iii. Occupational

- d. Analysis
- e. References

III. Toxicology

- a. Human data, case reports, and epidemiological studies
- b. Experimental animal information
- c. *In vitro* and other short-term tests
- d. Other relevant information
- e. References

IV. Disposition and Structure-Activity-Relations

- a. Absorption, distribution, metabolism, and excretion
- b. Structure-activity correlations and considerations
- c. References

V. Ongoing Toxicological and Environmental Studies in the Government, Industry, and Academia

VI. Rationale for Recommendation and Suggested Studies

# Appendix

# STATUTORY AUTHORITIES TO CONTROL TOXIC SUBSTANCES IN TWELVE MAJOR ACTS

Prepared by

Hollis Call

The following charts are intended to provide a summary representation of the statutory authorities to control toxic substances and the major information gathering/producing authorities contained in 12 selected acts.

## Limitations

These charts are designed to serve three essential purposes: one, to allow a quick reference of the statutory authorities contained in these 12 acts; two, to provide an overall picture of control authorities relevant to the lifecycle of a toxic substance; and three, to give an idea of some of the gaps, overlaps, and perhaps some of the legislative deficiencies present in the statutory framework for controlling toxic substances.

For each statute depicted in these charts, an appropriate Office or Agency administering that statute reviewed the material in a effort to make these charts as accurate as possible. However, for several reasons, there are some limitations on the use of this material.

First, this area of analysis is often very complex and further complicated by the fact that some of the statutory authorities shown in the charts have not yet been fully implemented or tested. Generally, a complete interpretation of the statutes' authorities can be accomplished only by reviewing the respective statutes, the Code of Federal Regulations, and any administrative or judicial judgments affecting the way in which these authorities are interpreted and used.

Another limitation that should be pointed out arises as a consequence of attempting to subsume what are often broadly stated authorities into discrete categories. Thus, the fact that several sections of different statutes may be listed in one box does not necessarily indicate that these sections can be equated. In most cases, they cannot. The additional analysis required to allow for direct comparison of these authorities is beyond the scope of this overview. However, a footnote is provided where the differences are particularly egregious. For convenience, only Chart 1 is footnoted; these footnotes apply as well to Charts 2 and 3.

## Observations

There are several preliminary observations that might be made from a reading of these charts.

One is that although there may be specific instances of a lack of statutory authority to control a toxic hazard, there do not appear to be many gaping holes in the statutory framework. As TSCA becomes fully implemented the comprehensive coverage of the toxic substance lifecycle will increase.

However, the existence of a full complement of statutory authorities does not ensure or indicate effective control of toxic substances. Over 30 pieces of legislation have some regulatory authority over toxic substances. Each piece in this statutory framework was added incrementally over the past 2 decades. Each piece of legislation was a response to specific perceived needs and thus each has a somewhat different orientation to toxic substance control, with different regulatory considerations.

The implications of these characteristics for regulating toxics, which typically fall under the jurisdiction of more than one statute, may be significant. Deficiencies in the regulatory coverage may arise as a result of conflicts between shared jurisdictions and a lack of integrated operational relationships between Agencies rather than simply an absence of statutory coverage. Whether these relationships present themselves as obstacles or conversely as opportunities will in part help determine whether toxic substances are controlled effectively and efficiently.

On the vertical axis are eight different types of regulatory action that a statute might authorize to control toxics. These types, or classes, of control actions are general and are not intended to be exhaustive of all regulatory or control options available. In many instances Agency efforts to control toxic substances are more subtle and indirect than the types of control actions listed in these charts. The Federal Insecticide, Fungicide, and Rodenticide Act's (FIFRA's) "rebuttable presumption against registration," for example, plays an important role in the regulatory fabric for regulating toxics, a role which is difficult to depict in these charts. Nevertheless, the types of control actions listed represent the predominant regulatory actions undertaken by Agencies to control toxic substances.

It should also be pointed out that there will be cases of overlap between these types of control actions. For example: a "guideline" or "standard" could be similar in effect to a "quantity limitation" of even a "prohibition," depending on how the standard was written and the response of the affected party. Distinctions between these authorities is based, in these charts, on a reading of the language in the statutes themselves.

The types of control actions listed in this chart should be self-descriptive. However, additional elaboration of the distinction between "labeling/packaging" and "notice" refers to the authority to require a specified party to give notice to those specifically exposed to a toxic hazard from a chemical substance or product which is in use, distribution, disposal, etc. "Labeling" authorities on the other hand generally refer to requirements for labeling of products to reduce or eliminate the risk from a toxic chemical substance or product prior to potential exposure through distribution, use, transportation, or disposal.

Chart 1

The horizontal axis of this chart contains eight columns which represent eight "points" in the lifecycle of a toxic substance. As such these points reflect both potential health or environmental exposure pathways, and potential points of regulatory control of a toxic substance.

Although the distinction made in these charts between manufacturing/processing, commercial distribution, transportation, use, etc., serves a useful analytical purpose, there may be overlap among these in some statutory provisions. Prohibiting or banning manufacturing/processing of a chemical, for example, would probably also have a similar effect on the end use of that chemical. On the other hand, a probibition/ban on manufacturing of a chemical for a particular use would still allow manufacturing and use of that chemical for non-banned uses. A decision by an Agency to control a toxic substance in either manufacturing, in use, or in manufacturing for a particular use, will depend largely upon the authorities available, the nature of the risk presented, and required regulatory considerations.

Charts 2 and 3

These charts contain the same information as Chart 1, but the information is referenced differently for user convenience. Chart 2 allows the reader to easily find any particular statute, control authorities. The lifecycle points to which each cited section of the statute applies are listed to the right of each section.

Chart 3 also allows referencing by statute, in this case according to points of lifecycle of a toxic substance. In this chart, the symbols representing the relevant control type are listed to the right of each section cited.

In both Charts 2 and 3, a legend appears at the bottom of the page referring to either types of control action (Chart 3) or chemical lifecycle (Chart 2).

Chart 4

Direct control actions taken by Agencies represented in these charts (Charts 1 thru 3) does not give a complete picture of the legislative framework to control toxic substances. Another signficant class of authorities which complement control actions are provisions for gathering/producing information. Chart 4 contains selected information gathering/producing authorities in these 12 Acts. The information in this chart display was taken in part from an EPA publication, Chemical Reporting and Record-Keeping Authorities Under 15 Environmental and Consumer Acts.

| CHART 1 | MANUFACTURING/ PROCESSING | COMMERCIAL DISTRIBUTION | EMISSIONS, EFFLUENTS | TRANS– PORTATION | IMPORTS | END USE (PRODUCTS) | STORAGE/ DISPOSAL | WORKPLACE EXPOSURE |
|---|---|---|---|---|---|---|---|---|
| PROHIBITIONS/ BANS | TSCA 5(e), (f);[1]<br>6(a)<br>CAA 211(c)<br>CPSA 19(a)(1),(2) | TSCA 6(a)(1);<br>6(a)(2)<br>CAA 211(c)<br>CPSA 8; 19(a)(1),<br>(2)<br>FIFRA 6; 12(a); 13(a)<br>FFDCA 301(a), (d)<br>FHSA 4(a),(f) | CWA 307(a)(2)<br>306<br>311(b)(1)(B)<br>SDWA 1424(a) | TSCA 6(a)(1);[4]<br>6(a)(2)<br>CPSA 8; 19(a)[5]<br>HMTA 105(a) | TSCA 13(a)(b)<br>FIFRA 6; 12(a); 13(a)<br>CPSA 17(a)<br>FHSA 14(a)<br>FFDCA 801(a) | CPSA 8<br>TSCA 6(a)(2)(A);<br>6(a)(5)<br>FIFRA 6;12(a);13(a)<br>FHSA 2(q)(1)(A)(B) | TSCA 6(a)(6)<br>RCRA 3004, 3005 | OSHA 13(a)[8] |
| QUANTITY LIMITATIONS | TSCA 5(f);<br>6(a)(2)<br>CPSA 9(d)(2)<br>CWA 301; 302; 304;<br>306 | TSCA 6(a)(1);<br>6(a)(2) | CAA 110(a)(2)(B)[3]<br>CWA 301<br>307(a)(2) | TSCA 6(a)(1);<br>6(a)(2)<br>HMTA 105(a)[6] | TSCA 6(a)(5)<br>CPSA 9(d)(2) | TSCA 6(a)(5) | | |
| GUIDELINES, STANDARDS, QUALITY CRITERIA | TSCA 6(b)(2)<br>CAA 111(b)(e)<br>RCRA 3002(2),(3) | | CWA 311(b)(1);<br>307(a)(2);<br>303;304;306<br>CAA 108;109;111(a);<br>112(b)(1);<br>160-169; 202<br>SDWA 1421; 1412 | FIFRA 19(b)[7]<br>RCRA 3003<br>HMTA 106(a)<br>CWA 311 | TSCA 6(b)(2)<br>CPSA 17(a)(1)<br>FFDCA 801(a) | CAA 202(a)(1)<br>CPSA 7(a)(1);<br>7(c)<br>FIFRA 3(d)<br>FFDCA 401; 406; 408<br>TSCA 6(a)(5) | CWA 307(a)(5)<br>FIFRA 19<br>RCRA 3004, 3005<br>4004, 1008<br>TSCA 6(a)(6) | OSHA 5(a);6(a);<br>6(b)(5);<br>6(c)(1);<br>20(a)(2),(3);<br>22 |
| REQUIRED LABELING/ PACKAGING PROVISIONS | TSCA 6(a)(3)[2] | TSCA 6(a)(3) | | TSCA 6(a)(3)<br>RCRA 3003(a)(2)<br>HMTA 105(a) | TSCA 13(a)<br>FIFRA 17(c)<br>CPSA 17(a)(2)<br>FHSA 14(a)<br>FFDCA 801(a) | TSCA 6(a)(3)<br>FIFRA 3(c)(5)(B)<br>CPSA 7;14(c);27(c)<br>FHSA 2(p);3(b)<br>PPPA 3<br>FFDCA 505(d)<br>502; 403; 602;<br>512(d)(1) | TSCA 6(a)(3)<br>RCRA 3002(2),(3)<br>3004 | OSHA 6(b)(7) |
| REGISTRATION CERTIFICATION OR PERMITS | CPSA 14(a)<br>CAA 165(a); 172(b)<br>FIFRA 7(a)<br>FFDCA 510 | CAA 211(a),(b);<br>203(a)(1)<br>FIFRA 3(a); 6<br>FFDCA 505; 512 | CWA 301(b)(2);<br>401; 402<br>SDWA 1421;<br>1424(b) | HMTA 106(b);<br>106(c)<br>RCRA 3003 | FIFRA 17(c)<br>CPSA 17(a)(2) | FIFRA 3(a); 4(a);<br>5; 6; 18<br>CPSA 14(a)<br>FFDCA 505<br>512<br>706<br>CAA 204; 211(b) | CWA 405<br>RCRA 3005 | |
| RECALL, REPLACE, REPURCHASE, SEIZURE | TSCA 6(a)(7)<br>CPSA 15(d)<br>FHSA 15(a)(1) | CPSA 15(d),(e)<br>FHSA 15(a)(2)<br>FIFRA | | | FIFRA 13 | TSCA 6(a)(7)<br>FIFRA 12; 13<br>CPSA 15(d),(c)<br>FHSA 6; 15(a)<br>FFDCA 304 | | |
| TO REQUIRE NOTICE OF HAZARDS TO THOSE EXPOSED | TSCA 6(a)(7) | | CWA 311 (b)(2) | | | CPSA 15 | | OSHA 6(b)(7);<br>8(c)(3);<br>13(c);<br>20(a)(b) |
| IMMINENT HAZARDS | TSCA 7 | CPSA 12<br>TSCA 7<br>FIFRA 6(c) | CWA 504<br>CAA 303; 311<br>RCRA 7003<br>SDWA 1431 | TSCA 7<br>RCRA 7003<br>HMTA 111(b)<br>CWA 311 | TSCA 13(a)<br>CPSA 17(a)(3)<br>FHSA 14(a)<br>FIFRA 6(c) | TSCA 7(a)(1)<br>FIFRA 6(c)<br>SDWA 1431(a)<br>CPSA 12<br>FHSA 2(q)(2); 3(a)(2)<br>FFDCA 505 (e);<br>512(e)(1) | TSCA 7(a)<br>RCRA 7003 | OSHA 13 |

| CHART 2 | PROHIBITIONS/ BANS | QUANTITY LIMITATIONS | GUIDELINES, STANDARDS, QUALITY CRITERIA (MANNER OR METHOD) | REQUIRED LABELING/ PACKAGING | REGISTRATION CERTIFICATION, OR PERMITS | RECALL, REPLACE REPURCHASE, SEIZURE | TO REQUIRE NOTICE TO THOSE EXPOSED | IMMINENT HAZARDS |
|---|---|---|---|---|---|---|---|---|
| CAA | 211(c) MP<br>211(c) CD | 110(a)(2) EE | 111(b),(e) MP<br>108 EE<br>109 EE<br>111(d) EE<br>112(b)(1) EE<br>160-169 EE<br>202 EE<br>202(a)(1) U | | 165(a) MP<br>172(b) MP<br>211(a),(b) CD<br>203(a)(1) CD<br>204 U<br>211(b) U | | | 303 EE<br>311 EE |
| CWA | 307(a)(2) EE<br>306 EE<br>311(b)(1) EE | 301 MP<br>302 MP<br>304 MP<br>306 MP<br>301 EE<br>307(a) EE | 303 EE<br>304 EE<br>306 EE<br>307(a)(2) EE<br>311(b)(1) EE<br>311 T<br>307(a)(5) D | | 301(h)(2) EE<br>401 EE<br>402 EE<br>405 D | | 311(b)(2) EE | 504 EE<br>311 T |
| FIFRA | 6;12(a);13(a) CD<br>6;12(a);13(a) I<br>17(a) I<br>6;12(a);13(a) U | | 19(b) T<br>3(d) U<br>19 D | 17(e) I<br>3(c)(5) U | 7(a) MP<br>3(a),(b) CD<br>17(a) I<br>3(a) U<br>4(a);5 U<br>6;18 U<br>U | 12 CD<br>13(a),(b) CD<br>12;13 U<br>13 I | | 6(c) CD<br>6(c) I<br>6(c) U |
| RCRA | 3004 D<br>3005 D | | 3002 MP<br>3003 T<br>1008 D<br>3004 D<br>3005 D<br>4004 D | 3003(a)(2) T<br>3002(2),(3) D<br>3004 D | 3003 T<br>3005 D | | | 7003 EE<br>7003 D |
| SDWA | 1424(a) EE | | 1412 EE<br>1421 EE | | 1421 EE<br>1424(b) EE | | | 1431 EE |
| TSCA | 5(e),(f) MP<br>6(a) MP<br>6(a)(1) CD<br>6(a)(2) CD<br>6(a)(1) T<br>6(a)(2) T<br>13(a)(b) I<br>6(a)(2) U<br>6(a)(5) U<br>6(a)(6) D | 5(f) MP<br>6(a)(2) MP<br>6(a)(1) CD<br>6(a)(2) CD<br>6(a)(1) T<br>6(a)(2) T<br>6(a)(5) I<br>6(a)(5) U | 6(b)(2) MP<br>6(b)(2) I<br>6(a)(4) U<br>6(a)(6) D | 6(a)(3) MP<br>6(a)(3) CD<br>6(a)(3) T<br>13(a) I<br>6(a)(3) U<br>6(a)(3) D | | 6(a)(7) MP<br>6(a)(7) U | 6(a)(7) MP | 7 MP<br>7 CD<br>7 T<br>13(a) I<br>7 U<br>7 D |
| CPSA | 19(a) MP<br>8 CD<br>19(a) CD<br>8 T<br>19(a) T<br>17(a) I<br>8 U | 9(a)(2) MP<br>9(d)(2) I | 17(a) I<br>7(a)(1) U<br>7(c) U | 17(a)(2) I<br>14(a) U<br>7 U<br>27(e) U | 14(a) MP<br>17(a)(2) I<br>14(a) U | 19(d) MP<br>15(d),(e) CD<br>15(d),(e) U | | |
| FPPA | | | | 3 U | | | | |
| FHSA | 4(a)(f) CD<br>14(a) I<br>2(q)(1)(A),(B) U | | | 14(a) I<br>3(b) U<br>2(P) U | | 15(a)(1) MP<br>15(a)(2) CD<br>6 U<br>15(e) U | | 14(a) I<br>3(a)(2) U<br>2(q)(2) U |
| OSHA | 13(a) W | | 5(a) W<br>6(a) W<br>6(b)(5) W<br>6(c)(1) W<br>20(a)(3) W<br>22 W | 6(a)(7) W<br>6(b)(7) W | | | 6(b)(7) W<br>8(c)(3) W<br>13(a) W<br>20(a)(5) W | 13 W |
| HMTA | 105(a) T | 105(a) T | 105(a) T | 105(a) T | 106(b)(a) T | | | 111(b) T |
| FFDCA | 301(a)(d) CD<br>801(a) I | | 801(a) I<br>401 U<br>406 U<br>408 U | 801(a) I<br>403 U<br>502 U<br>505(d) U<br>512(a)(1) U<br>602 U | 510 MP<br>505 CD<br>512 CD<br>505 U<br>512 U<br>706 U | 304 U | | 505(e) U<br>512(e)(1) U |

LEGEND:
MP: MANUFACTURING, PROCESSING
CD: COMMERCIAL DISTRIBUTION
EE: EMISSIONS/EFFLUENTS
T: TRANSPORTATION
I: IMPORTS
U: END USE (PRODUCTS)
D: DISPOSAL/STORAGE
W: WORKPLACE EXPOSURE

| CHART 3 | MANUFACTURING/ PROCESSING | COMMERCIAL DISTRIBUTION | EMISSIONS, EFFLUENTS | TRANSPORTATION | IMPORTS | END USE (PRODUCTS) | STORAGE/ DISPOSAL | WORKPLACE EXPOSURE |
|---|---|---|---|---|---|---|---|---|
| CAA | 211(c) P<br>111(b),(e) GS<br>105(a) RC<br>172(b)(6) RC | 211(c) P<br>211(a),(b) RC<br>203(a)(1) RC | 110(a)(2) QL<br>108 GS<br>109 GS<br>111(a) GS<br>112(b)(1) GS<br>160-169 GS<br>202 GS<br>303 IH<br>311 IH | | | 202(a)(1) GS<br>204 RC<br>211(b)(2) RC | | |
| CWA | 301 QL<br>302 QL<br>304 QL<br>306 QL | | 306 P<br>307(a)(2) P<br>311(b)(1) P<br>301 QL<br>307(a)(2) QL<br>311(b)(1) GS<br>307(a)(2) GS<br>303; 304 GS<br>306 GS<br>301(h)(2) RC<br>401; 402 RC<br>311(b)(2) N<br>504 IH | 311 GS | | | 307(a) GS<br>405 RC | |
| FIFRA | 7(a) RC | 6 P<br>12(a) P<br>13(a) P<br>3(a) RC<br>13(a),(b) RR<br>6 RC<br>12 RR<br>6(c) IH | | 19(b) GS | 17(c) P<br>17(c) LP<br>17(e) RC<br>12(a) P<br>13(a) P<br>6 P<br>13 RR<br>6(c) IH | 6 P<br>12(a) P<br>13(a) P<br>3(d) GS<br>3(c)(5) LP<br>3(a) RC<br>4(a) RC<br>5;6;10 RC<br>12;13 RR<br>6(c) IH | 19 GS | |
| RCRA | 3002(2),(3) GS | | 7003 IH | 3003 GS<br>3003(a) LP<br>3003 RC<br>7003 IH | | | 3004 P<br>3005 P<br>3002(2),(3) LP<br>3004 LP<br>3004 GS<br>3005 GS<br>4004 GS<br>1008 GS<br>3005 RC<br>7003 IH | |
| SDWA | | | 1424(a) P<br>1412 GS<br>1421 GS<br>1421 RC<br>1424(b) RC<br>1431 IH | | | 1431(a) IH | | |
| TSCA | 5(a),(f) P<br>6(a) P<br>5(f) QL<br>6(a) QL<br>6(b) GS<br>6(a)(3) LP<br>6(a)(7) N<br>7 IH | 6(a)(1)(A) P<br>6(a)(2)(A) P<br>6(a)(1)(B) QL<br>6(a)(2)(B) QL<br>6(a)(3) LP<br>7 IH | | 6(a)(1) P<br>6(a)(2) P<br>6(a)(1) QL<br>6(a)(2) QL<br>6(a)(3) LP<br>7 IH | 13(a),(b) P<br>6(a)(5) QL<br>6(a)(2) GS<br>13(a) LP<br>13(a) IH | 6(a)(2) P<br>6(a)(5) P<br>6(a)(5) QL<br>6(a)(5) GS<br>6(a)(3) LP<br>6(a)(7) RR<br>7 IH | 6(a)(6) P<br>6(a)(6) GS<br>6(a)(3) LP<br>7 IH | |
| CPSA | 10(a) P<br>9(d)(2) QL<br>14(a) RC<br>15(d) RR | 8 P<br>19(a) P<br>15(d),(e) RR<br>12 IH | | 8 P<br>19(a) P | 17(a) P<br>17(a)(1) GS<br>9(d) QL<br>17(a)(2) LP<br>17(a)(2) RC<br>17(a)(3) IH | 8 P<br>7(a)(1) GS<br>7(c) GS<br>14(c) LP<br>14(a) RC<br>15(d),(e) RR<br>15 N<br>12 IH | | |
| PPPA | | | | | | 3 LP<br>3 LP | | |
| FHSA | 15(a) RR | 4(a)(f) P<br>15(a)(2) RR | | | 14(a) P<br>14(a) LP<br>14(a) IH | 2(q)(1)(A),(B) P<br>3(b);2(p) LP<br>6 RR<br>15(a) RR<br>3(e) IH | | |
| OSHA | | | | | | | | 13(a) P<br>6(a) GS<br>6(b) GS<br>6(c) GS<br>20(a) GS<br>22 GS<br>6(b)(7) N<br>13 IH |
| HMTA | | | | 105(a) QL<br>108(a) GS<br>105(a) LP<br>106(b) RC<br>108(c) RC<br>111(b) IH | | | | 20(a)(2) GS<br>8(c)(3) N<br>13(c) N<br>20(a)(6) N |
| FFDCA | 510 RC | 301(a),(i) P<br>505 RC<br>512 RC | | | 801(a) P<br>801(a) GS<br>801(a) LP | 401 GS<br>406 GS<br>408 GS<br>403 LP<br>502 LP<br>505(d) LP<br>512(d) LP<br>602 LP<br>505 RC<br>512 RC<br>706 RC<br>304 RR<br>505(e) IH<br>512(e)(1) IH | | |

LEGEND

| | |
|---|---|
| P | PROHIBITIONS |
| QL | QUANTITY LIMITATIONS |
| GS | GUIDELINES, STANDARDS |
| LP | LABELING, PACKAGING |
| RC | REGISTRATION, CERTIFICATION |
| RR | RECALL, REPLACE, REPURCHASE |
| N | NOTICE REQUIREMENTS |
| IH | IMMINENT HAZARDS |

| CHART 4 | TSCA | RCRA | FIFRA | CAA | CWA | SDWA | FFDCA | OSHA | CPSA | FHSA | PPPA | HMTA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TESTING REQUIREMENTS | 4<br>5(a)<br>8(a)(4)<br>30 | 3001<br>3002 | 3(c)(1)(D)<br>5(d) | 111(j)(1)(A)<br>211(b)(1)(A) | | 1412<br>1421 | 409(b)(2)<br>505(b)<br>505(i)<br>512(b) | 6(b)(7)<br>20(a)(5) | 7(d)(3)(A)<br>14(a)<br>14(b) | | | |
| MONITORING (COMPLIANCE, EXPOSURE, HEALTH EFFECTS) | 6(a)(4)<br>8(b)<br>10(a) | 3004(2) | 3<br>20(b),(c) | 110(a)(2)(C)<br>110(a)(2)(F)(ii)<br>114(a)(1)<br>165(a)(7)<br>319 | 104(a)(5)<br>308(a)(8)<br>401(d) | 1413(a)(2)<br>1421(b)(1)(C)<br>1445(a) | 505<br>512 | 6(b)(7)<br>8(c)(3)<br>20(a)(5) | | | | 106(a) |
| INSPECTIONS RECORDS/ PREMISES | 8(c)<br>11(a),(b) | 3007 | 8(b)<br>9 | 114(a)(2) | 308(a)(B)<br>311(m) | 1413(a)(2)<br>1421(b)(1)(C)<br>1445(b)(1) | 505<br>512<br>702<br>704 | 8(a)<br>8(c)<br>8(g)(2)<br>18(c)(3)<br>19(a)(3)<br>19(d) | 7(d)(3)(C)<br>16(a)<br>16(b) | 11<br>12<br>14 | | 109(c) |
| PROVISIONS FOR TEST DATA SUBMISSION (AS PART OF REGISTRATION, CERTIFICATION, OR PERMIT PROCESS) | 4(g)<br>5(h) | 3004(7)<br>3005<br>3010(a) | 3<br>5<br>6(a)(2) | 110(a)(2)(D)<br>110(a)(4)<br>110(j)<br>111(j)(1)(A)<br>112(c)(1)(B)(ii)<br>165<br>165(a)(8)<br>172(b)(6)<br>173<br>211(b)(2) | 301(c),(g)<br>401(a)<br>402<br>403(a) | 1421(b)(1)(A)<br>1422(b)(1)(A) | 408<br>409<br>505<br>512<br>706 | | 10<br>27(e) | | | 106(b),(c)<br>107 |
| NOTIFICATION REQUIREMENTS (PREMANUFACTURE, PREMARKET, ETC.) | 5<br>6(a)(7)<br>8(b)(2)<br>7(b)(2)<br>8(e)<br>12(b) | 3002(4)<br>3010 | 12(a)(1)(P)<br>17(b) | 111(j)(1)(A)<br>165 | 311(b)(5)<br>311(c)(2)(D)<br>402(b)(8)<br>402(d) | 1414 | | | 13(a)<br>14(a)(1)<br>15(b)<br>15(c)<br>27(e)<br>14(c)(3) | | | |
| SUBMISSION OF REPORTS (OPERATIONS, OUTPUTS, HEALTH/ENVIR. EFFECTS, REQUIRED STUDIES) | 4(b)(1)<br>5(b)(2)(A)<br>5(d)(1)(A)<br>8(a)(2)<br>8(d) | 3002(6)<br>3004(2)<br>3005(b) | 3(c)(2)<br>5(d)<br>6(a)(2)<br>17(c)<br>11(a)<br>7 | 110(a)(2)(C)<br>110(a)(2)(F)(ii)<br>110(a)(4)<br>111(j)(1)(A)<br>165(a)(6)<br>165(e)(1)<br>172<br>211(b)(2)(B) | 305<br>308(a)(A)(ii) | 1413 | 505<br>512 | 8(c)(2)<br>18(c)(7)<br>18(c)(8)<br>20(a)(5)<br>19(a)(5) | 27(e) | | | 109(c) |
| INTERAGENCY COOPERATION FOR INFORMATION AND OTHER PURPOSES | 4(b)(2)(A)<br>6(c)<br>8(a)(3)(B)<br>9<br>9(d)<br>10<br>10(b)(1)<br>10(g)<br>26<br>27 | 1006<br>3003<br>6003<br>8001(a)<br>8001(b)<br>8002(f)<br>8003(f) | 3<br>6(b)<br>17(d)<br>21(a)<br>25(a)(2)<br>19<br>20<br>28 | 103<br>323(e)<br>402 (PL 95-95) | 102(a)<br>104<br>105<br>115<br>501(b) | 1442<br>1412 | 702(c)<br>702(d)<br>707 | 7(c)(1)<br>8(c)(3)<br>20<br>24<br>19(a)(4)<br>19(a)(5)<br>21 | 29 | 10(b) | | 105(b) |

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Bureau of Foods / Bureau of Drugs (FDA)
National Center for Toxicological Research (FDA)
National Cancer Institute (NIH)
National Institute of Environmental Health Sciences (NIH)
National Institute for Occupational Safety and Health

### Department of Labor

Occupational Safety and Health Administration

### Department of Transportation

Materials Transportation Bureau
United States Coast Guard

### Environmental Protection Agency

Office of Toxic Substances
Office of Pesticide Programs
Office of Water Planning and Standards
Office of Drinking Water
Office of Solid Waste
Office of Air Quality Planning and Standards / Office of Mobile Source Air Pollution Control

## PROGRAMS

National Toxicology Program